

1           IN THE UNITED STATES DISTRICT COURT  
2           FOR THE NORTHERN DISTRICT OF OHIO  
3           EASTERN DIVISION

4                           -   -   -

5  
6           IN RE:    NATIONAL                       :   HON. DAN A.  
7           PRESCRIPTION OPIATE               :   POLSTER  
8           LITIGATION                         :  
9   :   MDL NO. 2804  
10          APPLIES TO ALL CASES               :  
11   :   CASE NO.  
12   :   17-MD-2804  
13   :  
14   :

15                           - HIGHLY CONFIDENTIAL -  
16          SUBJECT TO FURTHER CONFIDENTIALITY REVIEW  
17                           VOLUME II

18                           -   -   -

19                           May 17, 2019

20                           -   -   -

21                           Continued videotaped  
22          deposition of DR. SETH B. WHITELOW, taken  
23          pursuant to notice, was held at the  
24          offices of Golkow Litigation Services,  
25          One Liberty Place, 1650 Market Street,  
26          Philadelphia, Pennsylvania, beginning at  
27          8:31 a.m., on the above date, before  
28          Michelle L. Gray, a Registered  
29          Professional Reporter, Certified  
30          Shorthand Reporter, Certified Realtime  
31          Reporter, and Notary Public.

32                           -   -   -

33                           GOLKOW LITIGATION SERVICES  
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24	VIDEOTAPE TECHNICIAN:	
	David Lane	

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8		Subject, Control IRR
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10		CVS-MDLT1-000101073
11	Whitelaw-19	E-mail Thread 801
12		2/7/14
13		Subject, Control/PSE
14		IRR
15		CVS-MDLT1-000008496-99
16	Whitelaw-20	E-mail Thread 805
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8		Notes, by Dr.
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<p style="text-align: right;">Page 538</p> <p>1                   - - -</p> <p>2           THE VIDEOGRAPHER: Back on</p> <p>3           the record.</p> <p>4           My name is David Lane,</p> <p>5           videographer for Golkow Litigation</p> <p>6           Services.</p> <p>7           Today's date is May 17,</p> <p>8           2019, and our time is 8:31 a.m.</p> <p>9           This deposition is taking</p> <p>10          place in Philadelphia,</p> <p>11          Pennsylvania, in the matter of</p> <p>12          National Prescription Opiate</p> <p>13          Litigation MDL.</p> <p>14          Our deponent today is</p> <p>15          Dr. Seth Whitelaw.</p> <p>16          Our counsel will be noted on</p> <p>17          the stenographic record.</p> <p>18          The court reporter today is</p> <p>19          Michelle Gray.</p> <p>20          Dr. Whitelaw, I just want to</p> <p>21          remind you, you're still under</p> <p>22          oath from yesterday.</p> <p>23          THE WITNESS: I understand.</p> <p>24</p>	<p style="text-align: right;">Page 540</p> <p>1          questions this morning.</p> <p>2          A. Good morning, Jennifer.</p> <p>3          Q. It's nice to meet you. So I</p> <p>4          want to start, Dr. Whitelaw, by asking</p> <p>5          you a couple of questions to make sure</p> <p>6          that I understand the scope of your</p> <p>7          opinions that you're offering about</p> <p>8          Cardinal Health in your reports. Okay?</p> <p>9          A. Okay.</p> <p>10          Q. So first of all,</p> <p>11          Dr. Whitelaw, you are not offering any</p> <p>12          opinions about any specific methodology</p> <p>13          that Cardinal Health -- you believe</p> <p>14          Cardinal Health should have used to</p> <p>15          identify suspicious orders, correct?</p> <p>16          MR. BOGLE: Object to form.</p> <p>17          THE WITNESS: Could you be a</p> <p>18          little more specific with that?</p> <p>19          Because I'm not sure where you --</p> <p>20          what you mean by methodology.</p> <p>21 BY MS. WICHT:</p> <p>22          Q. Do you understand that there</p> <p>23          are a variety of different ways that a</p> <p>24          registrant could identify suspicious</p>



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1 orders by -- placed by their customers?  
2 A. Are we talking about  
3 thresholds? Are we talking about  
4 systems? Again, methodology is a very  
5 broad term in the world that I work in.  
6 I need you to be -- I'm not trying to be  
7 difficult. Could you be a little more  
8 precise.  
9 Q. Sure. For example, a  
10 registrant could use a methodology like  
11 thresholds. A registrant could use a  
12 methodology that tracked growth over  
13 time. A registrant could use a variety  
14 of different calculations or  
15 methodologies in order to try to identify  
16 suspicious orders, correct?  
17 A. That is correct.  
18 Q. And you are not offering an  
19 opinion as to what particular methodology  
20 or any particular methodology Cardinal  
21 Health should have used --  
22 A. No, I'm not --  
23 Q. -- to identify suspicious  
24 orders?

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1 A. -- offering an opinion--  
2 MR. BOGLE: Just let her  
3 finish.  
4 THE WITNESS: Sorry.  
5 -- on a particular  
6 methodology as the way that you've  
7 just defined it.  
8 BY MS. WICHT:  
9 Q. Thank you. And you're not  
10 offering any opinions about any  
11 particular orders that were placed with  
12 Cardinal Health that you believe in your  
13 opinions were suspicious and not reported  
14 to DEA, correct?  
15 MR. BOGLE: Object to form.  
16 THE WITNESS: Again, I think  
17 we need to narrow what you're  
18 asking, because I'm not sure. You  
19 are asking a very broad question.  
20 Can we narrow it?  
21 BY MS. WICHT:  
22 Q. Have you identified -- do  
23 you have -- have you identified any  
24 specific order placed by a customer to

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1 Cardinal Health that you opine is  
2 suspicious and should have been reported  
3 to DEA but was not?  
4 MR. BOGLE: Object to form.  
5 THE WITNESS: Again, as I  
6 mentioned yesterday, and I'll  
7 reiterate for you today. I am a  
8 process and procedures and  
9 compliance expert. What I'm  
10 looking at is, what did you guys  
11 write down? Did you follow it?  
12 Is there a rationale behind the  
13 decisions that were made and does  
14 that rationale make any kind of  
15 sense? But that's what I'm  
16 working on.  
17 BY MS. WICHT:  
18 Q. So I understand that, and  
19 you mentioned yesterday that you're  
20 focused on process. And I appreciate  
21 that.  
22 What I'm trying to get at  
23 now, Dr. Whitelaw, is the question of  
24 whether -- and certainly you found flaws

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1 in Cardinal Health's suspicious order  
2 monitoring processes, correct?  
3 A. Yes, I did.  
4 Q. And we're going to -- we're  
5 going to get into those. But what I'm  
6 trying to get to now is the question of  
7 whether you identified whether those, in  
8 your opinion, flawed processes, whether  
9 you identified specific results that you  
10 contend were improper?  
11 MR. BOGLE: Object to form.  
12 BY MS. WICHT:  
13 Q. So my question is, are there  
14 any particular orders that were placed  
15 with Cardinal Health that you opine were  
16 suspicious and were not reported to DEA?  
17 MR. BOGLE: Object to form.  
18 THE WITNESS: I am going to  
19 go back to the four corners.  
20 Again I'm not quite sure what  
21 you're trying to -- trying to ask  
22 me, because it seems to me to be a  
23 two part question.  
24 I saw orders that Cardinal

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1 Health should have investigated  
2 further and didn't see any  
3 investigation on it.  
4 BY MS. WICHT:  
5 Q. Can you identify for me any  
6 particular order placed by a Cardinal  
7 Health customer that Cardinal Health, in  
8 your opinion, should have reported to DEA  
9 as suspicious and did not?  
10 MR. BOGLE: Object to form.  
11 Asked and answered.  
12 THE WITNESS: Again, as I  
13 said, I identified orders that I  
14 saw that should have generated  
15 additional due diligence. And  
16 what I saw was that that due  
17 diligence was not there.  
18 BY MS. WICHT:  
19 Q. If you had identified  
20 specific orders, an order placed by X  
21 customer on Y date, would those be  
22 included in your report?  
23 I'm sorry, let me -- let me  
24 rephrase that.

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1 If you had identified  
2 particular -- a particular order that you  
3 believed was suspicious and should have  
4 been reported to DEA and was not, would  
5 that be reflected in your report?  
6 A. Again, I am here as a  
7 compliance expert, not drawing legal  
8 conclusions. So again I'm not sure what  
9 you're asking me.  
10 Q. Can you identify for me any  
11 order placed by any customer to Cardinal  
12 Health that you believe was suspicious  
13 and was not reported to DEA?  
14 MR. BOGLE: If you need to  
15 refer to your report, you can.  
16 THE WITNESS: Let's go  
17 through the report. We can go  
18 through the report and look at the  
19 examples that are cited in my  
20 report. And I'm going to say --  
21 and I'm going to offer you the  
22 same answer that I gave you  
23 before, which is I saw things that  
24 should have generated additional

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1 inquiry by Cardinal Health. I did  
2 not see the additional inquiry  
3 being done.  
4 BY MS. WICHT:  
5 Q. So, respectfully my time  
6 this morning is limited. So I'm not  
7 going to take time to go through the  
8 report with you right now.  
9 But my question is, I take  
10 it from your answer then, that if you --  
11 to the extent you identified any  
12 suspicious orders that you contend should  
13 have been reported and were not, they  
14 will be identified in your report; is  
15 that correct?  
16 A. As I said yesterday, and I  
17 will make it clear again. The approach  
18 to the report is very similar to an  
19 audit. There are examples in there  
20 indicating, showing the pattern of  
21 practice with regards to process and  
22 failure to follow process. That's what's  
23 in my report.  
24 Q. And if there are no specific

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1 orders by any Cardinal Health customers  
2 identified in your report as suspicious,  
3 but not reported to DEA, then it's fair  
4 to assume that you did not identify any,  
5 correct?  
6 MR. BOGLE: Object to form.  
7 THE WITNESS: Again, let's  
8 go through the report and take a  
9 look at. I'm still having --  
10 struggling with your question.  
11 So, I'm sorry.  
12 BY MS. WICHT:  
13 Q. Are you offering any  
14 opinions, Dr. Whitelaw, concerning the  
15 specific thresholds that Cardinal Health  
16 set for any particular customer?  
17 MR. BOGLE: Object to form.  
18 THE WITNESS: Am I offering  
19 any opinions about the thresholds?  
20 BY MS. WICHT:  
21 Q. Are you --  
22 A. I -- you -- can you be more  
23 specific please?  
24 Q. Are -- yes. Are you

<p style="text-align: right;">Page 549</p> <p>1 offering any opinions about the  2 thresholds that Cardinal Health set for a  3 specific customer, in other words, are  4 you offering an opinion that the  5 threshold for a particular pharmacy was X  6 and it should have been X minus 100?  7 MR. BOGLE: Object to form.  8 BY MS. WICHT:  9 Q. Are you offering any  10 opinions of that nature with regard to  11 Cardinal Health?  12 MR. BOGLE: Same objection.  13 THE WITNESS: Again, as I've  14 tried to be clear, the opinions  15 I'm offering with regards to,  16 let's just take thresholds, would  17 have been what's the documentation  18 behind it to justify setting a  19 threshold at X.  20 BY MS. WICHT:  21 Q. So I understand, you're --  22 you're -- you've made clear that what  23 you're talking about is process.  24 What I'm trying to get to,</p>	<p style="text-align: right;">Page 551</p> <p>1 that I was asked to do, was look at  2 process, and whether the process was  3 followed. I am not drawing any legal  4 conclusions. I am simply noting the  5 process flaws and issues with the  6 current -- with the process that I  7 observed.  8 Q. I don't think I'm asking you  9 about any legal conclusions. I'm asking  10 you whether, as a factual matter, there's  11 any shipment of opioids by Cardinal  12 Health that you are opining was, in fact,  13 diverted to illegitimate use.  14 A. Again, you know the scope of  15 the report. It was outside of the scope.  16 I was not looking at that. I was looking  17 at the process and whether the process  18 was being followed.  19 Q. Okay. Now, your report,  20 sir, lays out a variety of ways that you  21 believe Cardinal Health's anti-diversion  22 program was not effective, correct?  23 A. Yes.  24 Q. And I take it from the</p>
<p style="text-align: right;">Page 550</p> <p>1 sir, is the outcome of that process.  2 I understand you believe  3 Cardinal Health's process for setting and  4 adjusting thresholds had flaws, correct?  5 A. Yes.  6 Q. Have you identified any  7 threshold for any Cardinal Health  8 customer that you believe was  9 inappropriately set --  10 A. Again --  11 MR. BOGLE: Just wait --  12 BY MS. WICHT:  13 Q. -- as a result of the  14 process flaws that you identified?  15 A. Again, outside the setting  16 of the actual number on whether it's  17 right or wrong, is outside of the scope  18 of what I was asked to look at.  19 Q. And you're not offering any  20 opinions as I understand it,  21 Dr. Whitelaw, that any particular  22 shipment of opioids by Cardinal Health  23 was, in fact, diverted, correct?  24 A. Again, my limit, the limits</p>	<p style="text-align: right;">Page 552</p> <p>1 testimony that you gave yesterday, that  2 you would agree with the premise that  3 there is no one correct way to run an  4 anti-diversion program, correct?  5 MR. BOGLE: Object to form.  6 THE WITNESS: I would agree  7 with the premise that any  8 anti-diversion program needs to be  9 tailored to the individual  10 company, which is consistent with  11 my experience as a compliance  12 expert and certainly fits with the  13 guidance that I have seen from the  14 DEA and others.  15 BY MS. WICHT:  16 Q. So anti-diversion systems or  17 practices, you would expect them to vary  18 from company to company, correct?  19 A. I would expect them to be  20 tailored appropriately to the -- from  21 company to company.  22 Q. And you would expect, even  23 the anti-diversion processes and systems  24 within one company to vary over time,</p>



<p style="text-align: right;">Page 553</p> <p>1 correct?</p> <p>2 MR. BOGLE: Object to form.</p> <p>3 THE WITNESS: What do you</p> <p>4 mean by "vary over time"?</p> <p>5 BY MS. WICHT:</p> <p>6 Q. You would expect them to</p> <p>7 change over time to account for changing</p> <p>8 circumstances, correct?</p> <p>9 MR. BOGLE: Object to form.</p> <p>10 THE WITNESS: Well, to</p> <p>11 clarify, I would expect to see if</p> <p>12 they are going to change, that</p> <p>13 there would be improvement over</p> <p>14 time.</p> <p>15 BY MS. WICHT:</p> <p>16 Q. So there's not, in your</p> <p>17 opinion, one correct form for an</p> <p>18 anti-diversion system against which you</p> <p>19 compared Cardinal Health and found them</p> <p>20 lacking, correct?</p> <p>21 MR. BOGLE: Object to form.</p> <p>22 BY MS. WICHT:</p> <p>23 Q. That wasn't the nature of</p> <p>24 the analysis that you did?</p>	<p style="text-align: right;">Page 555</p> <p>1 BY MS. WICHT:</p> <p>2 Q. You testified yesterday</p> <p>3 about companies speaking with the</p> <p>4 regulators who oversee their activities.</p> <p>5 Seeking guidance from the regulators who</p> <p>6 oversee their activities. Do you recall</p> <p>7 that subject generally from yesterday?</p> <p>8 A. I do recall that subject</p> <p>9 generally.</p> <p>10 Q. Okay. And I believe you</p> <p>11 testified that you were aware that some</p> <p>12 of the registrants involved in this case</p> <p>13 communicated with DEA from time to time</p> <p>14 to seek input about suspicious order</p> <p>15 monitoring, correct?</p> <p>16 A. I'd say that's a fair</p> <p>17 characterization.</p> <p>18 Q. And I believe you also</p> <p>19 testified yesterday that there's</p> <p>20 nothing -- there's nothing improper about</p> <p>21 that, correct, about communicating with</p> <p>22 regulators and seeking guidance from</p> <p>23 them?</p> <p>24 A. No. There's nothing</p>
<p style="text-align: right;">Page 554</p> <p>1 MR. BOGLE: Object to form.</p> <p>2 Misstates testimony.</p> <p>3 THE WITNESS: Could you ask</p> <p>4 the question again? I lost the</p> <p>5 train of thought.</p> <p>6 BY MS. WICHT:</p> <p>7 Q. Sure. You are not -- the</p> <p>8 nature of your analysis was not to</p> <p>9 compare Cardinal Health's anti-diversion</p> <p>10 processes against one -- against a one</p> <p>11 correct formula for a program and find</p> <p>12 them wanting as compared to that one</p> <p>13 correct formula, correct?</p> <p>14 MR. BOGLE: Objection.</p> <p>15 Misstates the testimony.</p> <p>16 You can answer.</p> <p>17 THE WITNESS: As I said,</p> <p>18 there is -- the standard is the</p> <p>19 same for having -- you have to</p> <p>20 have an effective anti-diversion</p> <p>21 program. That is going -- how you</p> <p>22 implement that will vary from</p> <p>23 company to company. It must be</p> <p>24 tailored to the company.</p>	<p style="text-align: right;">Page 556</p> <p>1 improper about doing it. As I said</p> <p>2 before, good communication is important.</p> <p>3 Q. Okay. So -- and I</p> <p>4 understand that we had a discussion</p> <p>5 yesterday about whether or not regulators</p> <p>6 should respond to those types of</p> <p>7 communications. And I'm not going there.</p> <p>8 I'm leaving that to the side.</p> <p>9 My question for you, though,</p> <p>10 is, if the regulator does respond and</p> <p>11 provides information or guidance back to</p> <p>12 the registrant, would you agree that the</p> <p>13 registrant should be able to rely on</p> <p>14 what's said to them by the regulator?</p> <p>15 MR. BOGLE: Objection.</p> <p>16 Vague and overbroad.</p> <p>17 THE WITNESS: Could you be a</p> <p>18 bit more precise, please?</p> <p>19 BY MS. WICHT:</p> <p>20 Q. Sure. So if, for example, a</p> <p>21 registrant has a conversation with a</p> <p>22 regulator about the nature of their</p> <p>23 suspicious order monitoring systems, and</p> <p>24 the regulator says, you're doing the</p>

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1 right thing, you're headed in the right  
 2 direction.  
 3 Do you agree that the  
 4 company should be able to rely on that  
 5 statement from the regulator?  
 6 A. I think you're going to have  
 7 to give more context to what that  
 8 communication looks like before I can  
 9 give you a response.  
 10 Do you have a specific fact  
 11 pattern, or is there a document that  
 12 you'd like me to look at?  
 13 Q. Well, should the  
 14 registrant -- when a registrant  
 15 communicates with DEA, are they entitled  
 16 to assume that DEA is not lying to them  
 17 in response?  
 18 MR. BOGLE: Object to form.  
 19 THE WITNESS: Again, can  
 20 we -- you're talking about all  
 21 communications, any kind of  
 22 contact. I think we need to  
 23 narrow that field, and what in  
 24 particular are you looking at? Do

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1 you have a particular fact pattern  
 2 that you'd like me to talk about?  
 3 Or is there a particular document  
 4 that you'd like me to work with?  
 5 BY MS. WICHT:  
 6 Q. I'm talking about  
 7 communications with DEA concerning  
 8 suspicious order monitoring practices.  
 9 If a registrant has a  
 10 communication with DEA about their  
 11 suspicious order monitoring practices, is  
 12 the registrant entitled to rely on  
 13 whatever information or input DEA  
 14 provides back to them?  
 15 MR. BOGLE: Object to form.  
 16 Vague and overbroad.  
 17 THE WITNESS: All right.  
 18 Let me try to ask some questions  
 19 that might help me answer your  
 20 question.  
 21 Is there a particular person  
 22 or position that we are talking  
 23 about that communication  
 24 occurring? Are we talking at the

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1 investigator level? The district  
 2 office level? Headquarters level?  
 3 When you say DEA, they employ a  
 4 large number of employees. So I'm  
 5 having trouble figuring out what  
 6 you're really seeking information  
 7 on.  
 8 BY MS. WICHT:  
 9 Q. Does it matter? Are  
 10 registrants entitled to rely on  
 11 headquarters but not entitled to rely on  
 12 field agents or vice versa?  
 13 A. I think as I tried to make  
 14 clear yesterday, policy -- when you're  
 15 looking for policy pronouncements, those  
 16 need to come from headquarters. And  
 17 those usually do come from headquarters.  
 18 Again, it does happen.  
 19 People are people. If you get something  
 20 that didn't make sense or the answer that  
 21 you get doesn't make sense compared to  
 22 what you know the policy is, then you  
 23 need to seek clarification up the chain  
 24 of command until you get a policy

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1 response.  
 2 Q. I want to talk about your  
 3 report for -- turn to your report,  
 4 Dr. Whitelaw, which is marked as  
 5 Exhibit 2.  
 6 A. Is there a specific page?  
 7 Q. On Page 45.  
 8 A. I'm there.  
 9 Q. In the last paragraph before  
 10 Section 8.2, you offered the opinion that  
 11 Cardinal Health, among other customers,  
 12 scored no higher than the midpoint of the  
 13 foundational level on your compliance  
 14 maturity and program effectiveness model,  
 15 correct?  
 16 A. That's what I opined, yes.  
 17 Q. When you offered that  
 18 opinion, are you -- does your opinion  
 19 relate to the suspicious order monitoring  
 20 program, the controlled substances  
 21 compliance program, or the corporate  
 22 compliance program as a whole? And I'm  
 23 referring to the three components of your  
 24 Russian nesting dolls.

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1 A. And I would say it relates  
2 to all three components because they're  
3 all interrelated and all interconnected.  
4 Q. Okay. So you're offering an  
5 opinion about Cardinal Health's -- not  
6 just Cardinal Health suspicious order  
7 monitoring program, but also its  
8 controlled substances compliance program  
9 and its corporate compliance program,  
10 correct?  
11 A. Again, as we've talked about  
12 under the Russian nesting dolls, if  
13 one -- you can't claim you have an  
14 effective -- we'll start at the top of  
15 the house. You can't claim that you have  
16 an effective corporate compliance program  
17 if you do not have an effective  
18 anti-diversion program, and if you do not  
19 have an effective suspicious order  
20 monitoring program. They all nest  
21 together. They're all interrelated.  
22 They're all interconnected.  
23 Q. So as part of your  
24 evaluation of Cardinal Health's overall

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1 controlled substances compliance program,  
2 did you make any evaluation of the  
3 company's practices with respect to  
4 physical security for opioids?  
5 A. Again, I was looking  
6 primarily -- the focus was suspicious  
7 order monitoring and moving from there.  
8 So again, if the suspicious order  
9 monitoring program is a problem, the  
10 anti-diversion program is not a -- can't  
11 be deemed to be effective, neither can  
12 the corporate compliance program be  
13 deemed effective. That is the opinion  
14 that I am offering.  
15 Q. Okay. So then, I take it  
16 from your answer then, that things  
17 outside of the suspicious order  
18 monitoring component of the controlled  
19 substances compliance program, you did  
20 not look at, correct?  
21 MR. BOGLE: Object to form.  
22 THE WITNESS: To your  
23 specific question about whether I  
24 looked at physical and vault

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1 security, I did not.  
2 BY MS. WICHT:  
3 Q. Did you look at Cardinal  
4 Health's compliance with regulations  
5 related to security and transport of  
6 opioids?  
7 A. I did not. It was outside  
8 of the scope of what I was asked to look  
9 at.  
10 Q. Did you look at Cardinal  
11 Health's practices with respect to theft  
12 and loss of controlled substances?  
13 A. Again, it was not in the  
14 scope of what I was asked to look at.  
15 Q. So what I'm trying to  
16 understand versus going through all of  
17 these individually, is that you did not  
18 look at compliance practices and  
19 processes outside of the suspicious order  
20 monitoring function; is that correct?  
21 MR. BOGLE: Object to form.  
22 Misstates the report.  
23 THE WITNESS: I think the  
24 better way to characterize it, to

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1 try to be helpful to you, is the  
2 focus was on suspicious order  
3 monitoring, as well as those  
4 things in the anti-diversion  
5 program and those in the corporate  
6 compliance program that would bear  
7 on it.  
8 Again, as I've said before,  
9 this is an integrated system. And  
10 so trying to tease out one bucket  
11 versus another bucket versus  
12 another bucket, which is why the  
13 diagram is drawn the way it is,  
14 you cannot separate them from each  
15 other. They are an integrated  
16 whole.  
17 BY MS. WICHT:  
18 Q. So fair to say that you did  
19 not evaluate practices or processes in  
20 Cardinal Health's compliance program  
21 except to the extent that they related to  
22 suspicious order monitoring, correct?  
23 MR. BOGLE: Object to form.  
24 THE WITNESS: I think that

<p style="text-align: right;">Page 565</p> <p>1 misstated what I said to the 2 extent that it related to or 3 impacted on suspicious order 4 monitoring, I did evaluate those. 5 BY MS. WICHT: 6 Q. Well, that's what I said. 7 To the extent that they related to 8 suspicious order monitoring. 9 A. And I'm adding the term "or 10 impacted" to be precise with you. 11 Q. Okay. If you would turn to 12 Page 100 of your report, please. 13 This is your section that's 14 specific to Cardinal Health, correct? 15 A. Yes. 16 Q. And on Page 100 and 101 you 17 refer to a couple of enforcement actions 18 against Cardinal Health. Do you recall 19 that? 20 A. Yes, ma'am, I do recall 21 referring to those enforcement actions. 22 Q. Now, none of the enforcement 23 actions against Cardinal Health that you 24 discuss occurred in Cuyahoga County or</p>	<p style="text-align: right;">Page 567</p> <p>1 THE WITNESS: Yes, I'm aware 2 of that. 3 BY MS. WICHT: 4 Q. Now, you testified about 5 Section 10.2 of your report is the 6 executive summary as to Cardinal Health, 7 correct? 8 A. Yes, that's what it states. 9 Q. And if I understood your 10 testimony yesterday, this section is 11 basically an attempt to summarize, 12 provide an executive summary of the 13 detail regarding Cardinal Health that 14 follows in the rest of the section; is 15 that correct? 16 A. I would say that is correct. 17 Q. Okay. And you -- so some of 18 your opinions that you summarize in the 19 executive summary about Cardinal Health, 20 one of your opinions is that Cardinal 21 Health was over reliant on technology in 22 controlled substances compliance efforts? 23 A. May I ask -- may I ask where 24 you're reading from?</p>
<p style="text-align: right;">Page 566</p> <p>1 Summit County, Ohio, correct? 2 A. That is correct. 3 Q. And none of the -- well, do 4 you know what -- which Cardinal Health 5 distribution center primarily served 6 Cuyahoga County and Summit County? 7 A. I'd have to go back and look 8 at my report, but not off the top of my 9 head, I do not. 10 Q. Okay. If I tell you it was 11 Wheeling, West Virginia, does that sound 12 familiar to you or do you think that's 13 something that you were aware of? 14 A. If you tell me Wheeling -- 15 Wheeling, West Virginia, the name sounds 16 familiar, but again I cannot, without 17 doing more digging definitively answer 18 your question for you. 19 Q. And are you aware that none 20 of the enforcement actions against 21 Cardinal Health that you refer to in your 22 report concern the Wheeling, West 23 Virginia, distribution center? 24 MR. BOGLE: Object to form.</p>	<p style="text-align: right;">Page 568</p> <p>1 Q. Yes, sir. Page 101. The 2 first full paragraph on the page. 3 A. I see the paragraph. I'm 4 there. 5 Q. And -- and one of your 6 opinions is that Cardinal Health's over 7 reliance on technology played a prominent 8 role in what you believe to be the 9 failure of its controlled substance 10 compliance program, correct? 11 A. I believe it played a role, 12 yes. 13 Q. And then if we go down to 14 the next paragraph below that, which is 15 just a one-sentence paragraph, you say, 16 "In the case of technology, Cardinal 17 placed a premium on its analytical 18 systems to detect suspicious orders and 19 potential diversion while neglecting the 20 importance of the human element and 21 making sense from the data outputs." 22 Do you see that? 23 A. Yes, I do. 24 Q. And that's your opinion?</p>

<p style="text-align: right;">Page 569</p> <p>1 A. That is my opinion.  2 Q. So I want to turn, sir, to  3 some of the detail about Cardinal Health  4 provided in your report. And if you  5 would turn to Page 117, please.  6 A. I'm there.  7 Q. If you look at the second  8 paragraph on that page, you may recall we  9 talked about this a bit yesterday where  10 you identify the fact that Cardinal's  11 process doesn't define significantly  12 larger, significantly more frequent, and  13 significant deviation. Are you with me?  14 A. I'm there.  15 Q. Okay. And then you say, "In  16 all" -- at the end of that paragraph:  17 "In all three cases, the standard  18 operating procedure just required QRA  19 personnel to use available information  20 and experience to make reportability  21 determinations."  22 Do you see that?  23 A. I do.  24 Q. And if you look at the</p>	<p style="text-align: right;">Page 571</p> <p>1 THE WITNESS: No, that's not  2 correct.  3 The issue wasn't the fact  4 that it asked the QA -- RA  5 personnel to use available  6 information and experience. The  7 problem with the SOP is it doesn't  8 provide any kind of boundaries or  9 guidelines on what available  10 information to look -- look at and  11 how to make those decisions. So  12 there's no decisionmaking  13 criteria. There's no set of  14 documents to evaluate. There's no  15 consistent process to be applied  16 which leads to inconsistency in  17 decisions between one person and  18 another person, if you don't  19 provide any sort of boundary lines  20 or goalposts. That's -- that's  21 basic compliance work, is to try  22 to create consistency in the  23 systems. You do that by putting  24 out criteria for people to follow,</p>
<p style="text-align: right;">Page 570</p> <p>1 beginning of that section on the report,  2 it appears to me that the time frame that  3 your criticism is directed at is from  4 2008 through 2016. Would you agree with  5 that?  6 A. Where are you looking  7 please?  8 Q. I'm looking at the beginning  9 of that Section B, "Threshold Events."  10 You say, "During this period Cardinal  11 Health implemented certain SOPs and they  12 ultimately retired them in 2016"?  13 A. Could you restate -- could  14 you repeat -- repeat the question for me  15 please?  16 Q. Sure. So your criticism,  17 one of your criticisms on Page 117 is  18 that the SOP in your view was faulty in  19 that it required Cardinal Health's QRA  20 personnel to use available information  21 and experience to make decisions,  22 correct?  23 MR. BOGLE: Object to form,  24 misstates the document.</p>	<p style="text-align: right;">Page 572</p> <p>1 so that Person A and Person B  2 achieve the same outcome on the  3 same set of facts.  4 BY MS. WICHT:  5 Q. Okay. Well, so let's talk  6 about that, sir. On Page 124 of your  7 report. At the very top of the page, you  8 talk about some work instructions for  9 Cardinal Health anti-diversion personnel.  10 Do you see that, sir?  11 A. I do.  12 Q. And you fault the work  13 instructions, you find fault with the  14 work instructions for providing what you  15 call a loophole where employees had  16 discretion to release certain orders,  17 correct?  18 A. I'd say that's a fair  19 characterization.  20 Q. And do you recall that those  21 work instructions provide significant --  22 well, let me strike that.  23 Do you recall the guidance  24 that is provided in the work instructions</p>



<p style="text-align: right;">Page 573</p> <p>1 for when employees are able to release          2 over threshold orders?          3 A. I'd have to look at the          4 document. Do you have a document for me          5 to look at?          6 Q. Sure. You actually attached          7 it to your report, sir. It's in the          8 back. At Appendix D on Page 249. Or at          9 least you attached a snippet of it.          10 Are you there?          11 A. I'm getting there. Yeah,          12 I'm there. Thank you.          13 Q. Okay. Sure. So this isn't          14 the whole document, but I guess it's a          15 clip of it that you -- you felt          16 appropriate to attach to your report.          17 But these are the -- do you          18 recognize these to be the work          19 instructions that provide guidelines for          20 release of over threshold orders?          21 A. I recognize it to be a table          22 that is taken out of a multi-page          23 document called "The Work Instructions,"          24 yes.</p>	<p style="text-align: right;">Page 575</p> <p>1 release orders over threshold in their          2 discretion?          3 A. It provides some guidance.          4 It's not the complete guidance. As we've          5 discussed, it's a table of percentages          6 taken from a multi-page work instruction          7 document.          8 Q. Is it your opinion that the          9 guidance provided to employees on when          10 they could release over threshold orders          11 in their discretion was inadequate?          12 A. Again, I would have to          13 review the entire work instruction          14 documents. So if you have a copy of that          15 I'll be happy to look through it again.          16 Q. So the snippet of a document          17 that you chose to include in your report          18 is not sufficient for you to make that          19 determination; is that correct?          20 MR. BOGLE: Object to form.          21 THE WITNESS: The snippet of          22 the document that I included was          23 to show the threshold values. It          24 wasn't necessarily to describe all</p>
<p style="text-align: right;">Page 574</p> <p>1 Q. Do you recognize it to be          2 the portion of the work instructions          3 that, in fact, guides employees on          4 releasing -- the potential to release          5 orders that are over threshold?          6 A. Again, it's a snippet from a          7 multi-page document. It's a table with          8 allowable percentage upgrades to          9 thresholds. Yes, I do recognize that.          10 It's not the entire document.          11 Q. Agreed. It's -- it's what          12 you saw fit to include in the report.          13 And you agree that that          14 table provides guidance to employees in          15 terms of what and when they are          16 authorized to, in their discretion,          17 release orders over threshold, correct?          18 A. Can you say the question          19 again for me? You lost me somewhere          20 there.          21 Q. Sure. The -- the table that          22 you included in your report provides          23 guidance to Cardinal Health employees in          24 terms of when they are authorized to</p>	<p style="text-align: right;">Page 576</p> <p>1 the guidance provided in the work          2 instruction.          3 BY MS. WICHT:          4 Q. I'm not asking you about all          5 the guidance provided in the work          6 instructions, sir. I'm asking you about          7 the guidance provided about when          8 employees in their discretion could          9 choose to release orders over threshold.          10 As I understand your          11 testimony, you're telling me that the          12 portion of the information that you          13 included in your report is not sufficient          14 to allow you to form an opinion about          15 whether that guidance was adequate,          16 correct?          17 MR. BOGLE: Object to form.          18 THE WITNESS: I think as I          19 keep trying to convey to you you          20 need to look at the entire work          21 instruction.          22 BY MS. WICHT:          23 Q. But you didn't put the          24 entire work instruction in the table of</p>

<p style="text-align: right;">Page 577</p> <p>1 your report, correct?</p> <p>2 A. I didn't put the entire</p> <p>3 document of all the documents in my</p> <p>4 report, so I'm not exactly sure what your</p> <p>5 point is, Counselor.</p> <p>6 Q. You quote -- back on Page</p> <p>7 101 in the executive summary of your</p> <p>8 report. You quote some testimony by</p> <p>9 Mr. George Barrett, the former CEO of</p> <p>10 Cardinal Health on Page 101.</p> <p>11 Do you see that?</p> <p>12 A. Where are you looking in</p> <p>13 particular?</p> <p>14 Q. I'm looking at the indented</p> <p>15 block quotes on Page 101.</p> <p>16 A. I see them.</p> <p>17 Q. Did you review</p> <p>18 Mr. Barrett's -- the entirety of</p> <p>19 Mr. Barrett's testimony to Congress?</p> <p>20 A. Yes, as a matter of fact, I</p> <p>21 did read the entire document.</p> <p>22 Q. Okay. Do you recall</p> <p>23 Mr. Barrett testifying that Cardinal</p> <p>24 Health has terminated or refused to</p>	<p style="text-align: right;">Page 579</p> <p>1 to read the document.</p> <p>2 THE WITNESS: I'm going to</p> <p>3 read the whole document, so --</p> <p>4 BY MS. WICHT:</p> <p>5 Q. Okay. Then let's move on.</p> <p>6 Do you recall, without reading the entire</p> <p>7 document, Mr. Barrett testifying that</p> <p>8 Cardinal Health had terminated or refused</p> <p>9 to distribute controlled substances to</p> <p>10 over a thousand pharmacies?</p> <p>11 A. As I said before, I would</p> <p>12 need the whole document to refresh my</p> <p>13 recollection. But we apparently don't</p> <p>14 have time.</p> <p>15 Q. Okay. So you don't --</p> <p>16 sitting here right now, you don't recall</p> <p>17 that testimony?</p> <p>18 A. I can't recall it off the</p> <p>19 top of my head.</p> <p>20 Q. Sitting here today, do you</p> <p>21 recall Mr. Barrett's testimony on Page 5</p> <p>22 of his written testimony that from 2008</p> <p>23 to the present, Cardinal Health had</p> <p>24 stopped suspicious orders for the</p>
<p style="text-align: right;">Page 578</p> <p>1 distribute controlled substances to over</p> <p>2 a thousand pharmacies? Did you see that</p> <p>3 testimony?</p> <p>4 A. I'm sure I did see it. I</p> <p>5 read the whole document. But I would</p> <p>6 have to see it again to refresh my</p> <p>7 recollection.</p> <p>8 (Document marked for</p> <p>9 identification as Exhibit</p> <p>10 Whitelaw-14.)</p> <p>11 MR. BOGLE: What's the</p> <p>12 exhibit number?</p> <p>13 MS. WICHT: 14.</p> <p>14 BY MS. WICHT:</p> <p>15 Q. And I'll ask you to turn,</p> <p>16 sir, to Page 5 --</p> <p>17 A. May I have --</p> <p>18 Q. -- of that testimony.</p> <p>19 A. May I have a minute to</p> <p>20 review the whole document?</p> <p>21 Q. No. If you're going to read</p> <p>22 the whole document, I'm not going to ask</p> <p>23 the question. Because I don't have time.</p> <p>24 MR. BOGLE: You're entitled</p>	<p style="text-align: right;">Page 580</p> <p>1 shipment of hundreds of millions of</p> <p>2 dosage units of controlled substances?</p> <p>3 Do you recall that?</p> <p>4 A. Again, without looking at</p> <p>5 the document, I -- I've read a lot of</p> <p>6 documents. I can't precisely recall what</p> <p>7 he said, all of the statements in that</p> <p>8 testimony.</p> <p>9 Q. You're welcome to look at</p> <p>10 Page 5 of the written testimony, which is</p> <p>11 where those appear, sir, but I'm not</p> <p>12 going to ask you about anything else in</p> <p>13 the document, so I'm not going to have</p> <p>14 you take the time to read through the</p> <p>15 whole thing.</p> <p>16 But you opined in your</p> <p>17 report that -- well, let me -- let me</p> <p>18 strike that.</p> <p>19 Did you consider those</p> <p>20 facts, those two facts offered by</p> <p>21 Mr. Barrett in forming your conclusions</p> <p>22 Cardinal Health's suspicious order</p> <p>23 monitoring program?</p> <p>24 A. I'm sure I considered those</p>

<p style="text-align: right;">Page 581</p> <p>1 facts in looking again at Mr. Barrett's  2 testimony. I read his testimony from  3 beginning to end. So at some point it  4 had to have factored in.  5 Q. So would you agree that  6 those facts are relevant to your analysis  7 of whether Cardinal Health -- and I'm  8 quoting from Page 101 of your report --  9 that Cardinal Health developed a program  10 that was -- allowed Cardinal to "avoid  11 identifying orders as suspicious and  12 continue supplying customers that it knew  13 or should have known were engaging in  14 diversion-related behavior"?  15 A. Can you be more specific?  16 What are you looking for, Counsel?  17 Q. My question is, whether  18 those facts as testified to by  19 Mr. Barrett in Congress, do you agree  20 that those facts are relevant to your  21 conclusion that Cardinal Health was  22 attempting to avoid identifying orders as  23 suspicious and continue supplying  24 customers it knew or should have known</p>	<p style="text-align: right;">Page 583</p> <p>1 looked at the totality of the  2 record. And as I said to you, I  3 did read Mr. Barrett's testimony  4 as part of the record I looked at  5 in forming my opinions.  6 BY MS. WICHT:  7 Q. How many customers do you  8 think Cardinal Health should have cut  9 off, if it had an effective -- in your  10 view, effective suspicious order  11 monitoring system?  12 A. I'm not here to opine on a  13 specific number. As I said I was looking  14 at process and failure to follow process,  15 and whether the process was robust or  16 not. I have no way of knowing what the  17 right number of customers to be  18 terminated would have been.  19 Q. And I take it your answer  20 would be the same if I asked the question  21 about suspicious order reporting as  22 opposed to termination of customers,  23 correct?  24 MR. BOGLE: Object to form.</p>
<p style="text-align: right;">Page 582</p> <p>1 were engaged in diversion?  2 A. Well, again, you're --  3 information is always relevant and needs  4 to be considered. In this particular  5 case, I have no way of verifying  6 Mr. Barrett's statements one way or the  7 other.  8 I looked at the record of  9 the other -- the totality of the record,  10 including Mr. Barrett's statements in  11 coming -- in forming my opinions. I  12 didn't just form it off of a single piece  13 of paper.  14 Q. So when you opined that  15 Cardinal Health was attempting to avoid  16 identifying orders as suspicious and  17 continue supplying customers it knew were  18 diverting, did you consider the number of  19 customers that Cardinal Health has cut  20 off from supplying controlled substances?  21 MR. BOGLE: Objection.  22 Asked and answered. You can  23 answer again.  24 THE WITNESS: Again, I</p>	<p style="text-align: right;">Page 584</p> <p>1 THE WITNESS: Again, I  2 looked at process, whether you  3 followed the process, whether  4 there's enough to understand how  5 the process worked.  6 So my answer would be  7 exactly the same. I'm not here to  8 tell you what is the right number  9 of suspicious orders.  10 BY MS. WICHT:  11 Q. If you would turn, sir, to  12 Page 104 of your report. This is the  13 section of your report that's about your  14 opinions about Cardinal Health's culture?  15 A. Yes.  16 Q. Are you there?  17 A. I'm there.  18 Q. Okay. You refer in that  19 section on Page 105 in the last paragraph  20 to an e-mail sent by a McKesson team  21 member that says -- reports on a  22 conversation supposedly with Cardinal  23 Health where Cardinal Health said that it  24 does not report suspicious orders to DEA</p>

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<p>1 because there is no upside. 2 Do you recall that e-mail? 3 A. Yeah. I do recall the 4 e-mail. 5 Q. Did you review any testimony 6 about that e-mail that you can recall? 7 A. Again, I've reviewed a lot 8 of testimony, so I can't say if I've 9 reviewed a specific piece of testimony or 10 not. 11 Q. Fair enough. And you cited 12 that particular e-mail as an example in 13 your report of one of the flaws -- or of 14 Cardinal Health's flawed corporate 15 culture, correct? 16 A. I cited it as an example, 17 yes. 18 Q. Did you -- well, are you -- 19 you're familiar with a Cardinal Health 20 employee named Gilberto Quintero? 21 A. Yes, I am familiar with him. 22 Q. And -- and that -- looking 23 at your reliance list, I don't believe 24 you reviewed Mr. Quintero's testimony in</p>	<p>1 list, so I'll represent to you that it 2 appears to me that -- well, all I can say 3 is he's on your list. That should mean 4 that you reviewed his testimony, correct? 5 A. I reviewed his testimony. 6 Q. Okay. Do you recall 7 Mr. Reardon testifying that he never said 8 to Mr. Mahoney that Cardinal Health does 9 not report suspicious orders? 10 A. I do not recall it. But 11 again I've reviewed a lot of depositions 12 and testimony. So I can't say I recall 13 it off the top of my head. 14 Q. I'm happy to show it to you 15 if you'd like to see it. 16 A. Sure. 17 Q. Okay. 18 (Document marked for 19 identification as Exhibit 20 Whitelaw-15.) 21 MS. WICHT: Sorry, I'm not 22 trying to throw it at you. 23 BY MS. WICHT: 24 Q. This is Exhibit Number 15,</p>
Page 586	Page 588
<p>1 this case at all; is that correct? 2 A. Again, I would have to go 3 back to the reliance list. 4 Q. Feel free to do that, sir. 5 The list of depositions is on Page 276 6 and 277. 7 A. I don't see it on my list. 8 Q. Okay. So you didn't review 9 the testimony given by Mr. Quintero in 10 this matter then, correct? 11 A. To the best of my knowledge, 12 relying on my reliance list, no. 13 Q. Okay. So then, you're not 14 aware, I assume, since you didn't review 15 the testimony, that Mr. Quintero 16 testified that that statement by 17 Mr. Mahoney was not true, correct? 18 A. I am not aware of that 19 statement. 20 Q. Did you review any testimony 21 by Mr. Reardon regarding this e-mail? 22 A. Again, I'd have to go back 23 to the reliance list. 24 Q. And Mr. Reardon is on your</p>	<p>1 which is an excerpt from the testimony of 2 Steve Reardon, a former employee of 3 Cardinal Health. 4 Do you see that? 5 A. I do see that that's what it 6 represents and purports to be, yes. 7 Q. Okay. And on Page 38, which 8 we've provided for you, sir, you can feel 9 free to take a look at the -- the few 10 questions that come before that. You'll 11 see that Mr. Reardon is being questioned 12 about this document. 13 And do you see Mr. Reardon 14 answering questions saying that he did 15 not make the comment that's recited in 16 this e-mail? 17 A. If I can have a second, 18 Counselor, I'm... 19 Q. Sure. 20 A. Yes, I see that he said 21 that. 22 Q. And did you review any 23 testimony by Mr. Mahoney on this e-mail? 24 And I'll represent to you again that</p>

<p style="text-align: right;">Page 589</p> <p>1 Mr. Mahoney does appear in your list of  2 reliance materials.  3 A. I -- I know I reviewed  4 his -- some -- I reviewed his testimony.  5 I can't again recall a specific section  6 out of multiple pages.  7 Q. Are you -- do you recall  8 that Mr. Mahoney testified about this  9 e-mail, "I believe that in my writing  10 this, I misspoke and I was referring to  11 when they shut customers down because  12 they were suspicious customers."  13 Do you recall seeing that in  14 Mr. Mahoney's deposition testimony?  15 A. Again, I don't recall it.  16 (Document marked for  17 identification as Exhibit  18 Whitelaw-16.)  19 BY MS. WICHT:  20 Q. I'll mark it as Exhibit 16,  21 just so that you have it in front of you,  22 sir. Sorry.  23 So this is an excerpt from  24 the testimony of Mr. Mahoney.</p>	<p style="text-align: right;">Page 591</p> <p>1 A. Does not change --  2 MR. BOGLE: Let her finish.  3 THE WITNESS: That is  4 correct, it does not change my  5 opinion. Again, we are talking  6 about opinions that are offered  7 after the fact when they are  8 confronted with something that is  9 unpleasant. And there was no  10 attempt made for example, when the  11 original e-mail was written to  12 correct the misstatements that are  13 in the original e-mail.  14 BY MS. WICHT:  15 Q. Well, how do you know that?  16 A. I didn't see anything.  17 Q. Do you know that it doesn't  18 exist?  19 A. No, but I don't know that it  20 didn't -- that it exists or doesn't  21 exist. But I didn't see anything that  22 says there was any contemporaneous  23 attempt to correct the record. And if  24 this was a -- again, standard practice is</p>
<p style="text-align: right;">Page 590</p> <p>1 Do you see that?  2 A. Yes, I see that.  3 Q. And the discussion of the  4 document begins on Page 424, which we've  5 excerpted for you. And do you see, the  6 testimony that I quoted for you is on  7 Page 425?  8 A. I'm getting there. I see  9 it.  10 Q. My question for you, sir, is  11 if all of the participants in this  12 supposed discussion that's recounted on  13 Page 105 of your report deny the accuracy  14 of that e-mail, does that affect your  15 opinion that the e-mail supports the  16 conclusions in your report?  17 A. No, Counselor, it doesn't  18 change my opinion.  19 Q. So the fact that all three  20 individuals who were involved in that  21 conversation deny that it occurred as  22 reported here on Page 105 of your report  23 has no impact on your conclusions about  24 the e-mail?</p>	<p style="text-align: right;">Page 592</p> <p>1 if you misstate or you make a mistake of  2 this kind of magnitude in an e-mail, you  3 correct it with a follow-up, that is  4 standard practice. That's what I would  5 have expected to see. I did not see it  6 here.  7 Q. So are you then offering an  8 opinion that Mr. Mahoney, Mr. Reardon,  9 and Mr. Quintero all lied under oath?  10 A. No, ma'am.  11 Q. Is that what you're  12 testifying to here today?  13 A. No, ma'am, I'm not. We know  14 the e-mail exists. We know the statement  15 exists.  16 Q. Okay. You in your report,  17 you reach several conclusions about  18 Cardinal Health's standard operating  19 procedures, correct? And I'm referring  20 to -- I'll direct you to Section 10.5.1  21 of your report, which begins on Page 108.  22 A. Okay.  23 Q. And you say in the third  24 paragraph on that page, you describe</p>



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1 Cardinal Health's anti-diversion program  
 2 from 2007 to 2012 as convoluted and you  
 3 state that it was difficult to determine  
 4 across the five key SOPs that comprised  
 5 the program where one ends and the other  
 6 begins.  
 7 Do you see that opinion?  
 8 A. Yes, I do.  
 9 Q. And that's your opinion,  
 10 correct?  
 11 A. That is my opinion.  
 12 Q. Okay. Are you familiar with  
 13 Mr. Michael Moné, a Cardinal Health  
 14 employee?  
 15 A. Yes.  
 16 Q. And you are aware that  
 17 Mr. Moné had, as I think you described it  
 18 on Page 107, Mr. Moné had operational  
 19 responsibility for the controlled  
 20 substances program during this period of  
 21 time, correct?  
 22 A. I recall that, yes.  
 23 Q. Okay. And Mr. Moné was --  
 24 do you recall that Mr. Moné was listed as

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1 an approver on most of the standard  
 2 operating procedures that you reviewed  
 3 from this period of time?  
 4 A. I would have to go back and  
 5 look at the actual documents to confirm  
 6 that, Counselor. So no, I don't recall  
 7 it off the top of my head.  
 8 Q. Now, you didn't review any  
 9 testimony by Mr. Moné in connection with  
 10 your work in this case, correct?  
 11 A. Again, let's go back to the  
 12 reliance list.  
 13 Q. Well, I can represent to you  
 14 that he's not on the reliance list,  
 15 because -- are you aware that plaintiffs  
 16 chose not to take Mr. Moné's deposition  
 17 in this case?  
 18 A. No, Counselor, I was not  
 19 aware of that.  
 20 Q. Okay. So obviously if his  
 21 deposition wasn't taken, then you didn't  
 22 review it, correct?  
 23 A. Obviously.  
 24 Q. So you don't know whether

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1 Mr. Moné views the standard operating  
 2 procedures as convoluted, correct?  
 3 A. No, Counselor, I do not.  
 4 But the relevant statement -- what  
 5 you're -- the relevance here, from a  
 6 compliance perspective, is I, as an  
 7 outsider, or a new employee, put myself  
 8 in a new employee's shoes, should be able  
 9 to read the documents on their face and  
 10 understand them, and I'm afraid, as I  
 11 read them and I've read lots of SOPs in  
 12 my career, written lots of SOPs in my  
 13 career, I had trouble understanding it.  
 14 So if I'm having trouble  
 15 understanding it, I don't know how you  
 16 explain it to a more junior -- you know,  
 17 to the basic members of staff.  
 18 MS. WICHT: Move to strike  
 19 everything after, "No, Counselor,  
 20 I do not."  
 21 BY MS. WICHT:  
 22 Q. So SOPs are not directed at  
 23 the outside world, are they,  
 24 Dr. Whitelaw?

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1 MR. BOGLE: Object to form.  
 2 THE WITNESS: SOPs are  
 3 directed both internally and  
 4 externally. You write them for  
 5 two audiences normally. You write  
 6 them to instruct staff on what  
 7 they're doing. But you're also  
 8 writing them because you're going  
 9 to be evaluated on them by  
 10 regulators and others to show you  
 11 have a system, an adequate and  
 12 effective system and process in  
 13 place and that you're following  
 14 that process.  
 15 BY MS. WICHT:  
 16 Q. Now, you -- although you  
 17 didn't review any testimony by Mr. Moné,  
 18 obviously. You did review the testimony  
 19 of various individuals who reported to  
 20 Mr. Moné, correct?  
 21 A. I did.  
 22 Q. Including Mr. Morse,  
 23 Mr. Forst, a variety -- Mr. Rausch.  
 24 Do those -- are those names

<p style="text-align: right;">Page 597</p> <p>1 familiar to you as people who reported to  2 Mr. Moné?  3 A. Yes, those names are  4 familiar to me.  5 Q. You reviewed their  6 testimony, correct?  7 A. Yes.  8 Q. Okay. Do you recall seeing  9 any testimony by any of those individuals  10 that they didn't understand Cardinal  11 Health's SOPs?  12 A. Without reviewing each of  13 their individual testimonies again, off  14 the top of my head, I do not recall.  15 Q. If you would turn to your  16 reliance list and to the deposition  17 transcripts that you reviewed again, sir,  18 on Page 276 and 277.  19 A. 276, yes.  20 Q. Okay. Are you familiar with  21 an individual named Kimberly  22 Anna-Soisson, a director of regulatory  23 management at Cardinal Health?  24 A. I am -- that name does ring</p>	<p style="text-align: right;">Page 599</p> <p>1 A. The name doesn't ring a bell  2 Counselor. We can go down my reliance  3 list.  4 Q. Did you review her  5 deposition testimony?  6 A. If it's not on my reliance  7 list, then I did not review her  8 testimony.  9 Q. Okay. I'll represent that  10 it's not on the list.  11 And we already established  12 that you didn't review any testimony by  13 Mr. Quintero, the senior vice president  14 of QRA at Cardinal Health, correct?  15 A. Yes.  16 Q. And are you familiar with a  17 gentleman named Rich Ryu, spelled R-Y-U,  18 a director of advanced analytics in  19 Cardinal Health's quality and regulatory  20 affairs department?  21 A. Again, the name -- I've  22 reviewed so many documents from so many  23 people. I don't recall the name rightly.  24 Q. But you didn't review</p>
<p style="text-align: right;">Page 598</p> <p>1 a bell.  2 Q. But her deposition is not  3 one of the ones that you reviewed,  4 correct?  5 A. It's not on my list that I  6 can see.  7 Q. Are you familiar with a  8 former Cardinal Health employee named  9 Doug Emma, a manage -- excuse me -- a  10 manager within the regulatory department?  11 A. Again, without going through  12 the section and looking at all the names,  13 I don't remember the name off the top of  14 my head.  15 Q. Okay. And you didn't review  16 any deposition testimony by Mr. Emma,  17 correct?  18 A. I don't see it on my  19 reliance list.  20 Q. How about Shirleen Justice,  21 a new account specialist in quality and  22 regulatory affairs, did you review any  23 testimony -- are you familiar with  24 Ms. Justice, first of all?</p>	<p style="text-align: right;">Page 600</p> <p>1 Mr. Ryu's deposition transcript, correct?  2 A. Let me look at my reliance  3 list again.  4 Q. Sure.  5 A. No, Jennifer, I did not  6 review the testimony according to my  7 reliance list.  8 Q. Okay. How about Mr. Craig  9 Baranski, the director of operations for  10 the Wheeling, West Virginia, distribution  11 center at Cardinal Health? You didn't  12 review his testimony either, did you?  13 A. Again, I'm going to go back  14 through the list. Again, I don't see his  15 name on my list.  16 Q. Just two more. It's getting  17 a little tedious here. How about Ray  18 Carney, the director of independent  19 retail sales for the Wheeling, West  20 Virginia, distribution center at Cardinal  21 Health? Did you review his deposition  22 testimony?  23 A. Again, I don't see it on my  24 list.</p>

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1 Q. And how about Thomas  
 2 Convery, who was a pharmacy business  
 3 consultant that was in the sales  
 4 organization? Did you review his  
 5 testimony?  
 6 A. I don't see him on my list.  
 7 Q. Okay. So we've gone through  
 8 now a list of nine individuals from  
 9 Cardinal Health. Now, were you aware of  
 10 whether or not those individuals provided  
 11 testimony in this case?  
 12 A. Counselor, I don't rightly  
 13 recall the list of everybody who produced  
 14 testimony or not in this case. So like I  
 15 said, I've looked at so many depositions.  
 16 I can't tell you off the top of my head.  
 17 Q. So four of those individuals  
 18 worked directly in Cardinal Health's  
 19 anti-diversion program. And then there  
 20 was Mr. Moné, who was obviously the --  
 21 had operational responsibility for the  
 22 program.  
 23 Do you think it would have  
 24 been helpful to review testimony from

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1 those individuals before you reached  
 2 conclusions about Cardinal Health's  
 3 anti-diversion program?  
 4 MR. BOGLE: Object to form.  
 5 THE WITNESS: I --  
 6 Counselor, without knowing what's  
 7 in the depositions, I can't make a  
 8 statement one way or the other on  
 9 that.  
 10 BY MS. WICHT:  
 11 Q. Okay. Fair to say, if  
 12 you -- it's possible that if you reviewed  
 13 deposition testimony from those six  
 14 individuals or maybe even all nine of the  
 15 individuals who I listed about Cardinal  
 16 Health's anti-diversion program, do you  
 17 think it's possible that your opinions  
 18 would be different?  
 19 MR. BOGLE: Object to form.  
 20 THE WITNESS: Anything is  
 21 possible. But I don't see  
 22 anything that would have changed  
 23 my overall conclusion that the  
 24 SOPs, for example, were difficult

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1 and convoluted to read. That  
 2 would not have changed, depending  
 3 on what they had to say about it.  
 4 MS. WICHT: Move to strike  
 5 after -- everything after,  
 6 "Anything is possible."  
 7 BY MS. WICHT:  
 8 Q. So I want to go back to a  
 9 subject that you touched on previously a  
 10 moment ago. You testified yesterday, I  
 11 believe -- please correct me if I'm  
 12 wrong -- that DEA did not provide precise  
 13 definitions of unusual size, unusual  
 14 frequency, or substantial deviation from  
 15 a normal pattern. Do you recall that  
 16 testimony from yesterday?  
 17 A. I do.  
 18 Q. Generally?  
 19 A. Generally.  
 20 Q. Okay. And I think you  
 21 said -- again, please correct me if I'm  
 22 wrong -- that it would be impossible for  
 23 DEA to give a blanket definition of those  
 24 words, because it's too fact dependent;

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1 is that correct?  
 2 A. That's not exactly -- that  
 3 is not what I said. What I said is DEA  
 4 does not give that, because they're  
 5 writing a regulation. My understanding,  
 6 they're writing a regulation for multiple  
 7 different companies and multiple  
 8 different business models. And so the  
 9 regulation is written in more general  
 10 terms.  
 11 Q. And then you were asked  
 12 about the fact that Cardinal Health's  
 13 SOPs used the words "significantly  
 14 larger." That's on Page 117 of your  
 15 report.  
 16 A. I see it.  
 17 Q. And I believe your testimony  
 18 yesterday was that you believed that,  
 19 unlike DEA, who is writing for the entire  
 20 registrant community, you believed that  
 21 Cardinal Health should be able to provide  
 22 additional granularity in its SOPs since  
 23 they only relate to Cardinal Health's  
 24 customers; is that correct?

<p style="text-align: right;">Page 605</p> <p>1 A. I believe Cardinal Health  2 should know Cardinal Health's customers  3 and be able to provide some criteria of  4 what those generic terms mean, yes.  5 Q. Now, as you recited in your  6 report, Cardinal Health has -- serves  7 more than 26,000 pharmacies, correct?  8 A. What page are we on?  9 Q. 100.  10 A. I see it.  11 Q. And again, as you describe  12 it in your report in the paragraph above  13 that, those customers might include  14 hospitals, correct?  15 A. They might.  16 Q. And pharmacies, correct?  17 A. They might.  18 Q. Both retail, independents,  19 and chains?  20 A. That's certainly plausible.  21 Q. And healthcare systems,  22 correct?  23 A. Yes.  24 Q. Ambulatory surgery centers,</p>	<p style="text-align: right;">Page 607</p> <p>1 time --  2 MR. BOGLE: If you want  3 to -- you want to withdraw the  4 question, that's fine. He's going  5 to answer it, otherwise. Your  6 call.  7 MS. WICHT: I withdraw the  8 question.  9 BY MS. WICHT:  10 Q. Is it your opinion that the  11 26,000 pharmacy customers that Cardinal  12 Health serves are all approximately the  13 same size?  14 MR. BOGLE: Object to form.  15 THE WITNESS: Again, as I  16 was saying, you are missing the  17 point.  18 The point here is there  19 needs to be more granularity to  20 very imprecise terms to provide  21 appropriate guidance to the staff  22 responsible for suspicious order  23 monitoring.  24 BY MS. WICHT:</p>
<p style="text-align: right;">Page 606</p> <p>1 correct?  2 A. Correct.  3 Q. Clinical laboratories,  4 correct?  5 A. Correct.  6 Q. And physician offices,  7 correct?  8 A. Potentially.  9 Q. And do you believe, of the  10 26,000 pharmacy customers that you cite  11 in your report, are all those customers  12 all approximately the same size, do you  13 believe?  14 MR. BOGLE: Object to form.  15 THE WITNESS: I think you  16 are missing the point.  17 The point was --  18 BY MS. WICHT:  19 Q. I -- I -- respectfully,  20 sir --  21 MR. BOGLE: You can answer  22 the question.  23 BY MS. WICHT:  24 Q. -- I have very limited</p>	<p style="text-align: right;">Page 608</p> <p>1 Q. Sir --  2 A. That's my point.  3 Q. Sir, I appreciate that you  4 want to jump to the end and give the  5 speech that you want to give. But the  6 way that this works is that I ask  7 questions and you answer the questions  8 that are asked. You don't get to just  9 jump ahead to the end. So let me ask my  10 question one more time.  11 Is it your opinion as you  12 sit here today, that the 26,000 pharmacy  13 customers that Cardinal Health serves are  14 all approximately the same size?  15 MR. BOGLE: Object to form.  16 THE WITNESS: I did not give  17 an opinion one way or the other on  18 the 26,000 customers that --  19 BY MS. WICHT:  20 Q. Fair.  21 And the definition of  22 suspicious order is the same for all  23 customers, correct?  24 A. The regulatory definition is</p>

<p style="text-align: right;">Page 609</p> <p>1 the same for what constitutes a          2 suspicious order.          3 Q. So, is it your opinion that,          4 as you sit here today, that Cardinal          5 Health should have been able to write a          6 standard operating procedure that          7 provided granularity as to the definition          8 of a suspicious order for 26,000          9 different customers of diverse sizes and          10 types? Is that your opinion?          11 MR. BOGLE: Object to form.          12 THE WITNESS: Could you          13 repeat the question for me?          14 BY MS. WICHT:          15 Q. Sure.          16 Is it your opinion as you          17 sit here today that Cardinal Health          18 should have been able to write a standard          19 operating procedure that provided          20 granularity as to the definition of a          21 suspicious order for 26,000 different          22 customers of diverse sizes and types?          23 MR. BOGLE: Object to form.          24 THE WITNESS: Again, because</p>	<p style="text-align: right;">Page 611</p> <p>1 report. I can tell you.          2 I did.          3 Q. Where are you reading, sir?          4 A. If you happen to look on          5 114, the quote under establishing          6 thresholds.          7 Q. Okay. And that block quote          8 that you just directed me to on Page 114          9 reflects that, as one part of its process          10 to establish threshold limits, Cardinal          11 Health differentiated customers through          12 segmentation by size and/or specialty,          13 correct?          14 A. Yes, that's what I directed          15 you to.          16 Q. Okay. So Cardinal Health          17 did, in fact, group pharmacies by size          18 and specialty as part of their suspicious          19 order monitoring program, correct?          20 MR. BOGLE: Object to form.          21 THE WITNESS: Could you          22 restate the question?          23 BY MS. WICHT:          24 Q. Sure.</p>
<p style="text-align: right;">Page 610</p> <p>1 I think we were trying to discuss,          2 the point here is you can          3 classify, you can group, you can          4 do things to put pharmacies and          5 different pharmacies and different          6 business models into different          7 classes and then set thresholds          8 and other requirements based on          9 that.          10 What I'm saying is, just          11 having an open-ended,          12 significantly larger,          13 significantly greater, those are          14 incredibly imprecise terms. There          15 needs to be more precision around          16 those terms.          17 BY MS. WICHT:          18 Q. Did you review Cardinal          19 Health's policies and procedures to          20 determine whether they did, in fact,          21 group pharmacies by size and business          22 model as part of their suspicious order          23 monitoring system?          24 A. Let me flip through my</p>	<p style="text-align: right;">Page 612</p> <p>1 As part of the processes for          2 its suspicious order monitoring program,          3 Cardinal Health did, in fact,          4 differentiate customers through          5 segmentation by size and/or specialty,          6 correct?          7 A. Well, that's what the SOP          8 says is that's what you are supposed to          9 do.          10 Q. Okay. Dr. Whitelaw, do you          11 have a set of notes related to Cardinal          12 Health that you prepared as part of your          13 deposition prep?          14 A. Yes, I do.          15 Q. Did you review those notes          16 last night or this morning in preparation          17 for your deposition testimony today?          18 A. No, I did not.          19 MS. WICHT: Okay. We've          20 been going about an hour and ten          21 minutes. If we can take a break.          22 MR. BOGLE: Okay.          23 THE VIDEOGRAPHER: Going off          24 the record at 9:41 a.m.</p>



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1 (Short break.)  
2 THE VIDEOGRAPHER: We are  
3 back on the record at 9:57 a.m.  
4 BY MS. WICHT:  
5 Q. Dr. Whitelaw, I'm going to  
6 ask you questions about a few of the  
7 specific pharmacies that are identified  
8 in your report now.  
9 If you would turn to Page  
10 51, please.  
11 A. You said 51, correct?  
12 Q. Yes, sir, Page 51. Your  
13 section about CVS Store 3322.  
14 Do you see that?  
15 A. I do.  
16 Q. And in your report you note  
17 that Cardinal Health distributed  
18 hydrocodone to this CVS location,  
19 correct?  
20 A. That's what it says in the  
21 report, yes.  
22 Q. And this CVS Store 3322, as  
23 you note, is located on Brookpark Road in  
24 Cleveland, Ohio, correct?

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1 A. That's the address I had in  
2 the documents I saw, yes.  
3 Q. Do you know anything about  
4 the area surrounding that location, sir?  
5 MR. BOGLE: Object to form.  
6 THE WITNESS: Could you be  
7 more specific?  
8 BY MS. WICHT:  
9 Q. Have you ever been there?  
10 A. No, I have not.  
11 Q. Did you look it up on Google  
12 Maps as part of your work on this case?  
13 A. No, I did not.  
14 Q. Are you aware of whether  
15 there are any medical centers nearby that  
16 CVS location?  
17 A. No, I am not.  
18 Q. Are you familiar with a  
19 Saint Vincent Charity Medical Center  
20 nearby that pharmacy?  
21 A. No, I am not aware of it.  
22 Q. Are you familiar with a  
23 Veterans Affairs outpatient clinic that's  
24 about ten minutes away from that

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1 pharmacy?  
2 A. No, I am not.  
3 Q. Did you compare the volumes  
4 of hydrocodone and oxycodone at CVS 3322  
5 that are recited in your report, to  
6 volumes of noncontrolled substances that  
7 were distributed to that store?  
8 A. No, Counselor, I did not.  
9 Q. Did you review Cardinal  
10 Health's tableau files related to CVS  
11 Store 3322?  
12 A. No, I did not.  
13 Q. Are you aware of there -- of  
14 DEA taking any enforcement action against  
15 CVS Store 3322?  
16 A. I am not aware of that, no.  
17 Q. Are you aware of the  
18 pharmacy or any of its pharmacists having  
19 their license suspended related to  
20 controlled substances?  
21 A. Counselor, we can go through  
22 lots of documents. I looked at lots of  
23 documents. This store is offered up for  
24 the fact that when I look at the due

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1 diligence file from behind this store, I  
2 didn't see adequate documentation to  
3 explain any of the things, for example,  
4 or any of the contributing factors that  
5 you were talking about, such as distance  
6 from a hospital or geographic location,  
7 et cetera. I didn't see that. That was  
8 the point that I was making here.  
9 Q. You didn't review Cardinal  
10 Health's Tableau file, correct?  
11 A. No, I did not review  
12 Cardinal Health's Tableau file.  
13 Q. So you don't know what  
14 information about the pharmacy's  
15 contained there, correct?  
16 A. Again, I reviewed the due  
17 diligence files on this -- that I was  
18 provided on this particular pharmacy and  
19 I didn't see any of the information that  
20 you're talking about in the file that I  
21 recall.  
22 Q. Did you review any Cardinal  
23 Health documentation about the thresholds  
24 for this particular pharmacy?

<p style="text-align: right;">Page 617</p> <p>1 A. I'm sorry. I'm not sure I'm  2 following your question.  3 Q. Did you review any Cardinal  4 Health documentation about the  5 thresholds, the controlled substance  6 thresholds, that Cardinal Health set for  7 this particular CVS Store 3322?  8 A. Again, if it was in the due  9 diligence file, I reviewed it. If it  10 wasn't in the due diligence file, I did  11 not review it.  12 Q. Do you recall whether it was  13 or wasn't?  14 A. I don't rightly recall.  15 I've looked at -- as I've said I looked  16 at a lot of pharmacies. If you have  17 something in particular that you'd like  18 me to consider, please show it to me.  19 I'm happy to consider it now.  20 Q. So the question I was asking  21 you before, sir, was whether you're aware  22 of CVS Store 3322 or any of the  23 pharmacists who work there having  24 discipline against their licenses related</p>	<p style="text-align: right;">Page 619</p> <p>1 have cut off distributions to that  2 customer?  3 MR. BOGLE: Object to form.  4 THE WITNESS: As I said, my  5 opinion is limited to the fact  6 that if you looked at the volumes,  7 it should have triggered due  8 diligence. There should be a  9 robust due diligence file. I  10 reviewed the due diligence file  11 that was provided, and I found it  12 to be lacking. That was what I  13 was reviewing.  14 BY MS. WICHT:  15 Q. Based on that answer, and on  16 your report, then, I understand that you  17 are not offering an opinion that Cardinal  18 Health should have cut off distribution  19 of controlled substances to CVS  20 Store 3322, correct?  21 MR. BOGLE: Object to form.  22 THE WITNESS: What I'm  23 offering an opinion to is the  24 adequacy of the due diligence</p>
<p style="text-align: right;">Page 618</p> <p>1 to controlled substance dispensing.  2 A. And I'm going back to my --  3 Q. Are you aware of that?  4 A. I'm going back to my  5 original answer. I reviewed the due  6 diligence file. This pharmacy was  7 offered up in my report as an example of  8 poor due diligence -- documented due  9 diligence. That's why it's here.  10 Q. Sir, respectfully, I'm not  11 asking you what you reviewed. I'm asking  12 you, as you sit here today, whether you  13 are aware of any discipline against CVS  14 Store 3322 or any of its pharmacists in  15 connection with controlled substance  16 dispensing?  17 A. Counselor, as I've said and  18 I tried to be honest and open and  19 transparent with you, I've reviewed a lot  20 of files on a lot of different  21 pharmacies, and no, I don't recall it off  22 the top of my head.  23 Q. Are you offering an opinion  24 that CVS Store 3322, that Cardinal should</p>	<p style="text-align: right;">Page 620</p> <p>1 documentation that I was provided  2 and reviewed. And so I can't --  3 because of the documentation that  4 I have, I couldn't give you a  5 recommendation one way or the  6 other on the store.  7 I'm looking for adequate  8 documentation. I don't find it.  9 BY MS. WICHT:  10 Q. Do you -- are you offering  11 the opinion that CVS Store 3322 should  12 have been shut down by the DEA?  13 MR. BOGLE: Object to form.  14 Asked and answered.  15 MS. WICHT: No, I was asking  16 about Cardinal Health's.  17 MR. BOGLE: All right. He's  18 given you --  19 MS. WICHT: I'm asking about  20 DEA now.  21 MR. BOGLE: He's given you  22 the scope of his opinion though.  23 If you ask him essentially the  24 same question phrased a bunch of</p>

<p style="text-align: right;">Page 621</p> <p>1 different ways -- but you can burn 2 your time that way if you want. 3 Go ahead. 4 THE WITNESS: Could I have 5 the question again, please. 6 BY MS. WICHT: 7 Q. Are you offering the opinion 8 that CVS Store 3322 should have been shut 9 down by the DEA? 10 A. Well, for one thing, I don't 11 purport to speak for the DEA at all in my 12 report. It's not in the scope of my 13 review. And that is not what we were 14 covering here. Again, we were covering 15 the adequacy of the due diligence file 16 that Cardinal was responsible for and 17 that I reviewed. 18 Q. So I want to turn to CVS 19 Store 4800 on the next page, please. 20 A. Sure. 21 Q. And this store is located at 22 590 East Market Street in Akron, Ohio, 23 correct? 24 A. That is the -- what I</p>	<p style="text-align: right;">Page 623</p> <p>1 diligence file, I would have reviewed it. 2 Q. Are you familiar with the 3 Summa Health Emergency Department that's 4 four minutes from that CVS location? 5 A. Again, if it was in the due 6 diligence file, I would have reviewed it. 7 Q. So the due diligence files 8 that you're referring to for CVS 4800 and 9 CVS 3322, those were provided to you by 10 the plaintiff attorneys, correct? 11 A. At my request. 12 Q. At your request. 13 Understood. Did you review anything 14 outside of the due diligence file about 15 those two customers? 16 A. I have reviewed a lot of 17 documents, Counselor. I can't rightly 18 tell you what all I did. I reviewed lots 19 of documents. 20 Q. What can you name for me, as 21 you sit here today, having billed 22 1,200 hours to this case in the last 6 23 months, what can you name for me here 24 today that you reviewed about CVS 4800 or</p>
<p style="text-align: right;">Page 622</p> <p>1 learned from the files, yes. 2 Q. Have you ever been to that 3 location, sir? 4 A. I have not been to Akron, 5 no. I haven't had the pleasure. 6 Q. Are you aware of whether 7 there are any medical centers nearby CVS 8 Store 4800? 9 A. No, I am not. But again, 10 we're talking about the adequacy of the 11 due diligence file that was on record. 12 And what I reviewed was in your due 13 diligence files that were provided to me. 14 Q. Are you familiar with Summa 15 Rehab Hospital located across the street 16 from that CVS location? 17 A. I do not rightly recall it. 18 But again, if it was in the due diligence 19 file, I'm sure I saw it. 20 Q. Are you familiar with Akron 21 City Hospital, three -- excuse me, three 22 minutes from the location of CVS Store 23 4800? 24 A. Again, if it was in the due</p>	<p style="text-align: right;">Page 624</p> <p>1 CVS 3322 outside of the due diligence 2 files? 3 A. Counselor, I looked at a lot 4 of paper. I can't tell you a specific 5 document off the top of my head without 6 reviewing the report. But if you'd like 7 to walk through the report and all the 8 citations, we can do that. 9 Q. Okay. Well, that was going 10 to be my next question, sir. 11 Fair to say that anything 12 you relied on, you would have cited in 13 the report, correct? 14 MR. BOGLE: Object to form. 15 THE WITNESS: Fair to say 16 that I would have -- it would be 17 in the report. 18 BY MS. WICHT: 19 Q. And the question of whether 20 Cardinal Health should have ceased 21 controlled substances distributions to 22 CVS Store 4800, I take it your answer, as 23 it was for the other location, was going 24 to be that was outside the scope of your</p>

<p style="text-align: right;">Page 625</p> <p>1 review, correct?</p> <p>2 A. Again, I was not making an</p> <p>3 opinion on whether or not Cardinal should</p> <p>4 have terminated the store or ceased</p> <p>5 distribution to the store. What I was</p> <p>6 discussing was the due diligence</p> <p>7 activities about this particular store.</p> <p>8 Q. Okay. There's a couple more</p> <p>9 pharmacies discussed in your report. If</p> <p>10 you turn to Page 102, please.</p> <p>11 A. Sure.</p> <p>12 Q. Do you see there's a</p> <p>13 discussion there of a CareMed Pharmacy?</p> <p>14 A. I'm getting there. I see</p> <p>15 it.</p> <p>16 Q. That pharmacy is in Florida,</p> <p>17 correct, sir?</p> <p>18 A. That is correct.</p> <p>19 Q. Do you have any knowledge of</p> <p>20 any individual in Summit County or</p> <p>21 Cuyahoga County, Ohio, obtaining opioids</p> <p>22 that Cardinal Health distributed to</p> <p>23 CareMed Pharmacy?</p> <p>24 A. No, Counselor, I don't. But</p>	<p style="text-align: right;">Page 627</p> <p>1 Q. Sir, my question had nothing</p> <p>2 to do with policies. Nothing to do with</p> <p>3 policies.</p> <p>4 I have very limited time.</p> <p>5 I'm going to ask you again to please</p> <p>6 answer the questions that I ask.</p> <p>7 If you turn to Page 103 --</p> <p>8 A. I am trying to answer your</p> <p>9 question.</p> <p>10 Q. -- there is a pharmacy</p> <p>11 CVS 219 that's discussed in your report,</p> <p>12 correct?</p> <p>13 A. I see CVS Pharmacy 219.</p> <p>14 Q. And that pharmacy is located</p> <p>15 in Florida, correct?</p> <p>16 A. That pharmacy is located in</p> <p>17 Florida.</p> <p>18 Q. And you have no knowledge,</p> <p>19 sir, of any individual from Summit or</p> <p>20 Cuyahoga County, Ohio, receiving opioids</p> <p>21 that Cardinal Health distributed to</p> <p>22 Pharmacy 219, correct?</p> <p>23 A. Again, as I've stated to</p> <p>24 you, these pharmacies are examples of the</p>
<p style="text-align: right;">Page 626</p> <p>1 again your program was a national</p> <p>2 program. You did --</p> <p>3 Q. I -- you answered my</p> <p>4 question, sir.</p> <p>5 MR. BOGLE: You can -- you</p> <p>6 can finish your answer.</p> <p>7 THE WITNESS: You were --</p> <p>8 the program I looked at was on a</p> <p>9 national basis, so it involved</p> <p>10 pharmacies from all over the</p> <p>11 country. Therefore, how you</p> <p>12 treated and followed your policies</p> <p>13 or didn't follow your policies is</p> <p>14 relevant to this discussion for</p> <p>15 Summit and Cuyahoga County. But</p> <p>16 it's relevant to how you ran your</p> <p>17 program.</p> <p>18 And in this case I found the</p> <p>19 program lacking, because you</p> <p>20 had -- where you did have policies</p> <p>21 they were unclear. And where you</p> <p>22 had -- and on a number of</p> <p>23 occasions, you didn't follow them.</p> <p>24 BY MS. WICHT:</p>	<p style="text-align: right;">Page 628</p> <p>1 process and policies and failure to</p> <p>2 follow those processes and to design an</p> <p>3 adequate system which you ran on a</p> <p>4 national basis, they are examples, and</p> <p>5 that's why they are included in this</p> <p>6 report.</p> <p>7 Q. So you didn't actually</p> <p>8 answer my question at all that time.</p> <p>9 Is it correct that you have</p> <p>10 no knowledge of any individual from</p> <p>11 Summit County or Cuyahoga County, Ohio,</p> <p>12 receiving opioids that Cardinal Health</p> <p>13 distributed to pharmacy 2 -- pharmacy</p> <p>14 CVS 219 in Florida?</p> <p>15 A. I have no specific knowledge</p> <p>16 of anybody in Cuyahoga or Summit County</p> <p>17 receiving product from this particular</p> <p>18 CVS store.</p> <p>19 Q. I'm going to ask you a</p> <p>20 question about regulatory guidance, sir.</p> <p>21 I think a few times in your testimony</p> <p>22 you've referred to guidance from DEA in</p> <p>23 the form of letters or presentations or</p> <p>24 discussions, correct?</p>

<p style="text-align: right;">Page 629</p> <p>1 Do you recall very generally</p> <p>2 discussing that guidance?</p> <p>3 A. Yes, I do.</p> <p>4 Q. And it's correct, sir, that</p> <p>5 guidance, regulatory guidance is not law,</p> <p>6 correct?</p> <p>7 MR. BOGLE: Object to form.</p> <p>8 THE WITNESS: It's not</p> <p>9 statute. It's not regulations,</p> <p>10 that's true.</p> <p>11 BY MS. WICHT:</p> <p>12 Q. So if a registrant does not</p> <p>13 comply with guidance, the registrant is</p> <p>14 not breaking the law, correct?</p> <p>15 MR. BOGLE: Object to form.</p> <p>16 THE WITNESS: Again, I can't</p> <p>17 make a judgment one way or the</p> <p>18 other. I'd have to know more</p> <p>19 facts and circumstances to be able</p> <p>20 to opine on that.</p> <p>21 BY MS. WICHT:</p> <p>22 Q. Is it your opinion that</p> <p>23 there is some circumstance in which a</p> <p>24 failure to comply -- strike that.</p>	<p style="text-align: right;">Page 631</p> <p>1 "I'm not here to offer a legal</p> <p>2 opinion, but I'll be happy to tell</p> <p>3 you how guidance works for</p> <p>4 compliance officers if you'd</p> <p>5 like."</p> <p>6 That was not the question I</p> <p>7 asked. I'm moving on.</p> <p>8 MR. BOGLE: Are you still</p> <p>9 answering?</p> <p>10 THE WITNESS: I would still</p> <p>11 give an answer. Yes.</p> <p>12 MR. BOGLE: Finish your</p> <p>13 answer.</p> <p>14 THE WITNESS: My answer</p> <p>15 would be, we use guidance as a way</p> <p>16 of informing us on how to frame</p> <p>17 out and comply with regulations</p> <p>18 and statutes.</p> <p>19 It is useful information, we</p> <p>20 use it that way.</p> <p>21 BY MS. WICHT:</p> <p>22 Q. Does a guidance letter</p> <p>23 create a legal obligation?</p> <p>24 MR. BOGLE: Object to form.</p>
<p style="text-align: right;">Page 630</p> <p>1 Guidance does not have the</p> <p>2 force of law, correct?</p> <p>3 MR. BOGLE: Object to form.</p> <p>4 THE WITNESS: I am not here</p> <p>5 to offer a legal opinion. I'm</p> <p>6 going to tell you how we use</p> <p>7 guidance as a compliance officer</p> <p>8 if you'd like.</p> <p>9 BY MS. WICHT:</p> <p>10 Q. No thank you.</p> <p>11 A. I use guidance as --</p> <p>12 Q. Sir --</p> <p>13 A. -- as one way of looking --</p> <p>14 Q. Sir, I did not ask that</p> <p>15 question, sir.</p> <p>16 MR. BOGLE: You can finish</p> <p>17 your answer.</p> <p>18 MS. WICHT: He</p> <p>19 acknowledged --</p> <p>20 MR. BOGLE: Withdraw the</p> <p>21 question. Withdraw the question.</p> <p>22 MS. WICHT: He acknowledged</p> <p>23 that he was moving on to speak</p> <p>24 about a different topic. He said,</p>	<p style="text-align: right;">Page 632</p> <p>1 THE WITNESS: I'm not here</p> <p>2 to offer a legal opinion one way</p> <p>3 or the other on guidance</p> <p>4 documents. I'm here as a</p> <p>5 compliance expert.</p> <p>6 But I am going to tell you</p> <p>7 that if you don't --</p> <p>8 BY MS. WICHT:</p> <p>9 Q. Sir, I'd like to talk --</p> <p>10 A. -- if you don't follow</p> <p>11 guidance, you are running a risk as a</p> <p>12 company. That's what I would tell my</p> <p>13 clients and have told my clients.</p> <p>14 Guidance is useful and should be at least</p> <p>15 factored into the decisionmaking process.</p> <p>16 MS. WICHT: So, Counsel, I'm</p> <p>17 just putting you on notice right</p> <p>18 now, that I'm -- I'm going to hold</p> <p>19 the deposition open -- I'm going</p> <p>20 to move to strike all the</p> <p>21 nonresponsive speeches that the</p> <p>22 witness is giving. I'm going to</p> <p>23 hold the deposition open. I'm not</p> <p>24 going to conclude it today,</p>



<p style="text-align: right;">Page 633</p> <p>1 because he's not answering the  2 questions that are posed to him.  3 So I'm putting you on notice of  4 that right now. Let's move on to  5 something else.  6 MS. CASTLES: Join.  7 MS. MONAGHAN: Join.  8 MS. McCLURE: Join.  9 MR. BOGLE: I think he's  10 answering just fine. I think he's  11 answering just fine.  12 BY MS. WICHT:  13 Q. So I'd like to ask you a  14 question about Page 104 of your report,  15 sir. Going back to your discussion of  16 Cardinal Health's corporate culture.  17 A. I'm there.  18 Q. Okay. The first sentence of  19 Section 10.4.1 says, "Cardinal culture  20 was and continues to be myopically  21 focused on increasing revenues and  22 cutting costs."  23 Is that your opinion?  24 A. That is my opinion.</p>	<p style="text-align: right;">Page 635</p> <p>1 accountability. Do you recall that?  2 A. Yes.  3 Q. Okay. And that refers to  4 accountability for employees who, in your  5 opinion, performed inadequately in their  6 compliance functions, correct?  7 A. I would say that was one  8 facet of it. The other facet of  9 accountability had to do with how you  10 handle customers that don't follow or  11 won't give you documents, won't  12 provide -- provide help, won't follow  13 your procedures and procedures --  14 Q. Okay. So I'm --  15 A. -- or follow contracts. So  16 we're talking about both.  17 Q. I'm focused at the moment on  18 the issue of accountability for  19 employees. Okay?  20 A. Okay.  21 Q. So -- and I think you said  22 yesterday that accountability doesn't  23 necessarily require the termination of  24 an -- of an employee, correct, in your</p>
<p style="text-align: right;">Page 634</p> <p>1 Q. Are -- do you know anything  2 about Cardinal Health's program called  3 Generation Rx?  4 A. Not off the top of my head,  5 that I can recall, Counselor.  6 Q. You are not familiar with  7 that drug abuse and misuse prevention  8 program that Cardinal Health created in  9 partnership with the Ohio State  10 University College of Pharmacy?  11 A. Counselor, it was not  12 something I looked at and it was not part  13 of this report, no.  14 Q. Okay. All right. Do you  15 know anything about Cardinal Health's  16 opioid action program?  17 A. No, Counselor, I don't.  18 Q. Okay.  19 A. But if you have something  20 you'd like me to look at, I'd be happy to  21 look at it right now for you.  22 Is there a --  23 Q. You talked in your report  24 generally about the concept of</p>	<p style="text-align: right;">Page 636</p> <p>1 opinion?  2 A. I said accountability, there  3 were a range of options. Termination was  4 a possibility.  5 Q. Okay. And reduction in pay  6 or bonus, that was another possibility  7 that I think you mentioned?  8 A. All fact and circumstance  9 driven.  10 Q. Okay. And transfer to  11 another part of the organization, that  12 was another possible --  13 A. It was possible.  14 Q. Excuse me. Let me finish  15 the question. Thank you.  16 That's another -- excuse me.  17 Lost my train of thought.  18 Transfer to another part of  19 the organization is another possibly way  20 that a company could have accountability  21 for employees, correct?  22 A. It is another possibly way,  23 yes.  24 Q. Okay. You -- on Page 120 of</p>

<p style="text-align: right;">Page 637</p> <p>1 your report, sir, you discuss Cardinal  2 Health --  3 A. Which page are we on?  4 Q. 120, sir.  5 A. Okay. I'm there.  6 Q. You discuss Cardinal Health  7 notifying customers on their invoices  8 that their orders had been held pending  9 regulatory review. Do you recall that?  10 A. Is there a specific  11 paragraph on this page?  12 Q. Top paragraph. No, I'm  13 sorry, the third paragraph on the page.  14 "The customer will see on the invoice  15 held pending regulatory review."  16 Do you see that?  17 A. I do see that.  18 Q. Okay. Do you -- is it your  19 opinion that it was improper for Cardinal  20 to notify its customers that their  21 invoices were being held -- I'm sorry,  22 that their order -- orders were being  23 held pending regulatory review?  24 A. I didn't say it was</p>	<p style="text-align: right;">Page 639</p> <p>1 customer.  2 Q. Okay. I believe you  3 testified yesterday, sir, but please  4 correct me if I'm wrong, that you did  5 compliance program-related work for a  6 distributor who is named as a defendant  7 in this case; is that correct?  8 A. That was -- again, I have to  9 look at the transcript to remember  10 exactly what I said. But I believe that  11 is correct.  12 Q. Did that work include --  13 strike that.  14 Was that work in your  15 capacity as a consultant at your current  16 company?  17 A. No, it was not.  18 Q. In what capacity did you do  19 that work?  20 A. It would have been when I  21 was working for Deloitte, to the best of  22 my recollection.  23 Q. Okay. Did that work include  24 consulting on the distributor's</p>
<p style="text-align: right;">Page 638</p> <p>1 improper. What I said was it gave  2 customers a way of understanding what  3 their thresholds were without  4 communicating it directly. They could  5 back into the thresholds, and it was  6 something that needed to be factored in  7 and taken into account.  8 Q. I take it it was outside the  9 scope of your work in this case to  10 determine whether any customer actually  11 backed into their thresholds and used  12 that information to work around the  13 thresholds, correct?  14 MR. BOGLE: Object to form.  15 THE WITNESS: Again, I'm  16 speaking to the process.  17 BY MS. WICHT:  18 Q. So I think that's yes,  19 right, it was outside the scope of your  20 work in this case to determine whether  21 that actually happened with any specific  22 customer?  23 A. It was outside of my scope  24 to look at it in the case of a specific</p>	<p style="text-align: right;">Page 640</p> <p>1 suspicious order monitoring program?  2 A. Well, again, I'm not sure  3 which distributor we are talking about.  4 Can we be a little more precise?  5 Q. I'm talking about whichever  6 distributor you did work for.  7 A. Well, okay --  8 MR. BOGLE: If we can keep  9 it down over there, please, and be  10 respectful and professional.  11 MS. WICHT: I just -- let  12 the record reflect that the  13 witness is smiling as well. I --  14 nobody was --  15 THE WITNESS: I'm trying to  16 understand --  17 MR. BOGLE: It was on video.  18 You don't need to have the record  19 reflect anything.  20 MS. WICHT: I agree. It  21 will reflect that he was smiling.  22 MR. BOGLE: Whether he's  23 smiling has nothing to do with  24 whether 20 people are laughing out</p>

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1 loud while you're asking  
2 questions.  
3 BY MS. WICHT:  
4 Q. The compliance  
5 program-related work that you did for a  
6 distributor who is named as a defendant  
7 in this case, did it include consulting  
8 with respect to that distributor's  
9 suspicious order monitoring program?  
10 A. To the best of my  
11 recollection, Counselor, no it did not.  
12 Q. Okay. And if you look at  
13 Page 2 in your report, the second  
14 paragraph on that page says, "None of the  
15 organizations reviewed in this report  
16 have employed me or engaged the services  
17 of me and my firm." And my question is,  
18 is that a true statement?  
19 A. Yes, I believe it is a true  
20 statement.  
21 Q. Okay. Yesterday at one  
22 point during your testimony, you referred  
23 to the fact that you were working for the  
24 court. Do you recall saying that?

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1 A. I do recall saying that.  
2 Q. So I want to be clear about  
3 that, sir. You haven't been engaged by  
4 the court to serve as an expert in this  
5 case, correct?  
6 A. No, I have not.  
7 Q. You are engaged by plaintiff  
8 attorneys, correct?  
9 A. That is correct.  
10 Q. And it's not the court who  
11 owes you about \$480,000 at this point,  
12 correct? It's the plaintiff attorneys,  
13 correct?  
14 A. That is correct. However, I  
15 feel that I have an obligation to the  
16 court to do the very best work that I  
17 can, because it's not just plaintiffs'  
18 counsel that's reading it. You're  
19 reading it. The judge is going to be  
20 reading my report. So, therefore, I  
21 believe that there's an obligation to do  
22 the very best work possible.  
23 Q. How much of your current  
24 business is consulting for plaintiffs in

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1 this case?  
2 A. I don't rightly know off the  
3 top of my head.  
4 Q. Do you have other work  
5 currently?  
6 A. Yeah, I do currently.  
7 Q. Okay. Would you say that  
8 your consulting work for plaintiffs in  
9 this case is more than 50 percent of your  
10 current work?  
11 MR. BOGLE: Object to form.  
12 Asked and answered.  
13 THE WITNESS: As I said,  
14 Counselor, I don't have a precise  
15 number for you.  
16 BY MS. WICHT:  
17 Q. So you're the -- are you the  
18 sole employee of your business?  
19 A. Yes, Counselor, I am.  
20 Q. So you -- you manage it, you  
21 operate it, you do everything with  
22 respect to the business, correct?  
23 A. I do.  
24 Q. And you, as you sit here

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1 today, cannot tell me what percentage of  
2 your current business approximately is  
3 consulting for plaintiffs in this case,  
4 correct?  
5 MR. BOGLE: Objection.  
6 Asked and answered.  
7 THE WITNESS: Counselor, I  
8 can't.  
9 MS. WICHT: Okay. I have  
10 many, many more lines of  
11 questioning that I have not had  
12 time to get into today both  
13 because of the time constraints of  
14 the deposition, and because of  
15 respectfully, in my opinion, the  
16 answers that the witness has  
17 provided. In deference to my  
18 colleagues, who are on the defense  
19 side I'm going to pass the witness  
20 now. But I have more examination  
21 to do, and I am going to hold the  
22 deposition open and reserve the  
23 right to seek more time or other  
24 relief. If we can go off the

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1 record in order to hand over the  
2 mic please.  
3 THE VIDEOGRAPHER: Going off  
4 the record at 10:23 a.m.  
5 (Brief pause.)  
6 THE VIDEOGRAPHER: We are  
7 back on record at 10:29 a.m.  
8 - - -  
9 EXAMINATION  
10 - - -  
11 BY MR. MELTON:  
12 Q. Good morning, Dr. Whitelaw.  
13 A. Good morning.  
14 Q. My name is Jeffrey Melton,  
15 and I represent AmerisourceBergen Drug  
16 Corporation.  
17 A. Nice to meet you.  
18 Q. Nice to meet you as well.  
19 Before we really get started  
20 I wanted to follow up on one question  
21 that Ms. Wicht was asking you about her  
22 line of questions.  
23 A. Sure.  
24 Q. I thought I heard you

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1 testify yesterday that the compliance  
2 work that you had done for a defendant in  
3 this case, I thought I heard you say that  
4 it was ABC. Did I hear that correctly  
5 yesterday?  
6 A. No, I don't think you did.  
7 I'm not sure I said a defendant.  
8 Q. Okay. Is it possible that  
9 if I heard ABC, it was, you know, ABC,  
10 meaning a string of letters and not ABC  
11 meaning AmerisourceBergen Corporation?  
12 A. Again, I don't recall --  
13 without going back and looking at the  
14 testimony, I don't remember. But I don't  
15 recall saying I worked for a particular  
16 client. I think I was giving a series of  
17 clients as examples of clients that  
18 Deloitte served. But I don't think I was  
19 naming a specific client.  
20 Q. So it was not your intention  
21 to name ABC?  
22 A. It was not my intention. If  
23 you heard that that way, that was not my  
24 intention.

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1 Q. Have you ever done any work  
2 for AmerisourceBergen?  
3 A. Not that I can recall, no.  
4 Q. Is AmerisourceBergen one of  
5 the companies that's evaluated in your  
6 report that's marked as Exhibit 2?  
7 A. Yes, it is.  
8 Q. Is there a -- do you recall  
9 whether there is a review time period for  
10 the AmerisourceBergen section?  
11 A. Not off the top of my head.  
12 But I can go and flip to the section and  
13 look if you'd like.  
14 Q. That's okay. We'll get to  
15 it.  
16 A. Okay.  
17 Q. Did you review any documents  
18 that informed your opinion on ABC that  
19 you did not cite to in your report?  
20 A. I looked at a lot of  
21 documents. If I used it to support the  
22 positions that I -- it was in, it would  
23 have been in the report. But I can't  
24 rule out, I've looked at a lot of

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1 documents -- you know, I've looked at a  
2 lot of documents.  
3 Q. Did you review any documents  
4 that informed your opinion on ABC that  
5 you did not list --  
6 A. Not to the best of my --  
7 MR. BOGLE: Wait until he  
8 finishes.  
9 THE WITNESS: I'm sorry.  
10 Can you ask the question again?  
11 BY MR. MELTON:  
12 Q. Sure.  
13 A. I didn't mean to interrupt  
14 you.  
15 Q. Did you review any documents  
16 that informed your opinion on ABC that  
17 you did not list as reliance materials in  
18 your report?  
19 A. Not that I can recall, sir.  
20 Q. Okay. Let's -- let's take a  
21 look at Page 126 of your report that's  
22 marked as Exhibit 2.  
23 A. 126.  
24 Okay.

<p style="text-align: right;">Page 649</p> <p>1 Q. And this is the start of the 2 ABC section of your report, correct? 3 A. Mm-hmm, yes, it is. 4 Q. Okay. Can you flip to 5 Page 128? 6 A. I'm there. 7 Q. Okay. Now, on Page 128 8 approximately, it's -- it's in the third 9 paragraph, you use the phrase "bare 10 minimums," do you see that? 11 A. Yeah, I saw it. 12 Q. What do you mean by bare 13 minimums? 14 A. What I mean by bare 15 minimums, where you were doing just 16 enough, or trying to set up a program 17 that went just -- was just barely 18 effective. So you were doing the bare 19 minimums of what you needed to do. You 20 weren't trying to stand -- ABC was not 21 trying to stand out as a stellar 22 performer. They were just doing the 23 basics that they had to do to get by. 24 That's what I meant.</p>	<p style="text-align: right;">Page 651</p> <p>1 A. I think I'm there. 2 Q. Now, do you see the last 3 sentence before it says Clark Lowcost 4 Pharmacy, where it says, "Below are just 5 a few examples illustrating how ABC's 6 approach to its anti-diversion program 7 translated into various retail pharmacy 8 stores obtaining high levels of opioids 9 with little or no investigation or 10 interrogation." 11 Did I read that correctly? 12 A. Yes, you did read that 13 correctly. 14 Q. Clark Lowcost Pharmacy is 15 one such example? 16 A. Clark Lowcost Pharmacy was 17 one of the examples in the report, yes. 18 Q. And on the next page, on 19 Page 130, Church Square Pharmacy is 20 identified? 21 A. Yes. 22 Q. And is Church Square 23 Pharmacy a second example? 24 A. Yes, it is.</p>
<p style="text-align: right;">Page 650</p> <p>1 Q. So the minimum to meet the 2 regulations, but nothing more, is that 3 your testimony? 4 MR. BOGLE: Object to form. 5 THE WITNESS: The minimums 6 to meet your obligations and 7 nothing more. 8 BY MR. MELTON: 9 Q. Now, yesterday we talked a 10 lot about your chart that's on Page 43 of 11 your report. 12 A. I'm there. 13 Q. Where is the bare minimum 14 located on this chart, if you can tell 15 me? 16 A. The words "bare minimum" are 17 not on the chart. 18 Q. So from -- from left to 19 right on the chart, if you had to place 20 the bare minimum into one of the four 21 categories, where would it be? 22 A. Left, in the foundational. 23 Q. All right. Let's flip to 24 Page 129 of your report.</p>	<p style="text-align: right;">Page 652</p> <p>1 Q. Would you define two 2 customer examples as various retail 3 pharmacy stores as quoted from the 4 sentence just before Clark Lowcost 5 Pharmacy? 6 MR. BOGLE: Object to form. 7 THE WITNESS: I believe they 8 are retail pharmacies, yes. 9 BY MR. MELTON: 10 Q. Is it your opinion that two 11 examples of retail pharmacies would form 12 a pattern? 13 A. I'm saying I cited two 14 examples in my report. I think you can 15 start to see the pattern. I think there 16 is a pattern here. 17 Q. With two pharmacies there's 18 a pattern, that's what you're telling me? 19 A. I cited two pharmacies as 20 examples. There are other examples 21 potentially. But I'm saying, if -- if 22 you look, they are illustrative of the 23 issues discussed further on in the 24 report.</p>



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1 Q. Did you identify any other  
2 examples of pharmacies in your report for  
3 ABC?  
4 A. We can go through the whole  
5 section, but the only two I remember are  
6 these two off -- you know, in the  
7 front-end. But again I can go through my  
8 whole report if you'd like.  
9 Q. That's okay.  
10 Did you identify these  
11 pharmacies yourself?  
12 A. Yes, actually I did identify  
13 both of these pharmacies myself. Again,  
14 I asked counsel, as I testified to  
15 yesterday, for pharmacies in Summit and  
16 Cuyahoga County. I went through various  
17 files and I picked these two as  
18 illustrative examples.  
19 Q. But you didn't say to  
20 counsel, please give me the file for  
21 Clark Lowcost Pharmacy, did you?  
22 A. I asked counsel to give me  
23 files for pharmacies in Cuyahoga and  
24 Summit Counties that had high indications

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1 of opioid usage, serviced by ABC, as I  
2 did for the other defendants as well.  
3 Q. Other than Clark Lowcost  
4 Pharmacy and Church Square Pharmacy  
5 identified in your report, do you intend  
6 to offer any opinions for other ABC  
7 customers as examples of retail pharmacy  
8 stores obtaining high levels of opioids  
9 without investigation or interrogation?  
10 A. At this point in time  
11 without new evidence or facts to be  
12 considered, as again as I've said before,  
13 I hold my report open to reflecting new  
14 information. At this point in time I  
15 have no intention.  
16 Q. What do you mean by the term  
17 "interrogation"?  
18 A. What I meant by is asking  
19 the question why and trying to find the  
20 answer as to why. These are high levels  
21 of opioid usage and I didn't see an  
22 adequate interrogation as in why is this  
23 happening. There's not -- the  
24 documentation was not solid enough for me

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1 to make a determination that there was a  
2 close examination in an attempt to answer  
3 the question why. That to me is  
4 interrogation.  
5 Q. Is Clark Lowcost Pharmacy  
6 located in Cuyahoga County?  
7 A. According to my report, yes,  
8 it is.  
9 Q. And also according to your  
10 report, ABC completed a threshold review  
11 request for this pharmacy in  
12 October 2010; is that correct?  
13 A. Yes. I saw it.  
14 Q. And the threshold review  
15 request was submitted by Ron Kline,  
16 correct?  
17 A. Yeah. That's what the  
18 report says.  
19 Q. Have you ever spoken to  
20 Mr. Kline?  
21 A. No, I have not spoken  
22 directly to Mr. Kline.  
23 Q. Have you ever read any  
24 testimony from Mr. Kline?

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1 A. Well, let's go back to the  
2 reliance list. We can go down my  
3 deposition list. So I'd -- I'd have to  
4 look there to be able to tell -- answer  
5 your question. So if you can give me a  
6 minute.  
7 Q. If I told you he was not  
8 deposed in this case --  
9 A. I'd still like to check my  
10 own records if you don't mind.  
11 Q. Sure. It's 276 is where it  
12 starts.  
13 A. I know. I'm just trying to  
14 flip to the page. I don't see it on the  
15 list.  
16 Q. Did you interview anyone at  
17 ABC regarding this threshold request for  
18 Clark Lowcost Pharmacy?  
19 A. No, I did not approach  
20 anyone at ABC directly, no.  
21 Q. Did you review ABC's  
22 transactional data for Clark Lowcost  
23 Pharmacy?  
24 A. Again, if I reviewed it, and

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1 it was in the file, I would have reviewed  
2 it. I can't tell you off the top of my  
3 head other than what's in the report.  
4 Q. Okay. I'll represent to you  
5 that I did not see a reference to ABC  
6 transactional data in -- in your report.  
7 Did you review ABC's --  
8 A. Well, again, I think it  
9 depends on, Counselor, what we're talking  
10 about. I mean, I would need your help  
11 here to understand what you mean by  
12 transactional data, because I would say  
13 looking at threshold allotments and  
14 actual threshold amounts, that is  
15 arguably transactional data. So I'm not  
16 sure what you mean by transactional data.  
17 Q. Line-by-line sales data.  
18 A. Not that I recall.  
19 Q. Okay. Did you review ABC's  
20 Tableau files that were produced in this  
21 case?  
22 A. Again, not to my -- I don't  
23 have a recollection of it.  
24 Q. Now, looking at Page 129.

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1 Do you see, sort of in the middle of the  
2 page, where there's a one, two and three  
3 listed?  
4 A. I'm sorry, 129, you said?  
5 Q. Yep.  
6 A. Yes, I do.  
7 Q. Is it your opinion that a  
8 customer located within several miles of  
9 two hospitals is a red flag?  
10 A. I'm not saying it's a red  
11 flag. What I'm saying is it's something  
12 to be -- it's a factor to be considered  
13 looking at how you're setting thresholds.  
14 It's information.  
15 Q. Is it also a factor to be  
16 considered that a customer is located  
17 within several miles of a hospital with a  
18 pain clinic?  
19 A. Again, pain clinics are --  
20 have been considered red flags by the DEA  
21 in this whole, you know, in Florida and  
22 other places. So it is something -- it  
23 is another factor to factor in. It is  
24 certainly something to explore.

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1 Q. What is the basis of your  
2 statement that pain clinics have been  
3 identified as red flags by the DEA?  
4 A. I'd have to go back and pull  
5 the front of the report and go through  
6 the guidance. But I remember it being  
7 guidance. I don't have an exact  
8 reference for you.  
9 Q. So your testimony is that  
10 somewhere in your report --  
11 A. My testimony is, I believe,  
12 somewhere in the front of the report  
13 where we talk about DEA guidance, there  
14 is an indicia of diversion. And I  
15 believe it's in the Rannazzisi letters.  
16 But don't ask me to go farther and tell  
17 you which date unless you want me to  
18 spend some time -- your time looking it  
19 up.  
20 Q. No, that's okay. Do you  
21 recall yesterday testifying that you  
22 spoke to Mr. Rafalski, an expert in this  
23 case?  
24 A. I do.

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1 Q. Did you speak to  
2 Mr. Rafalski about red flags?  
3 A. I may have. I can't rightly  
4 recall whether we spoke -- I'm sure we  
5 did speak about it.  
6 Q. What do you recall about  
7 that conversation?  
8 A. I recall that we sort of  
9 talked about red flags in general. I  
10 think pain clinics were one of the things  
11 that he brought -- we discussed. I'm --  
12 beyond that. I can't recall. I cannot  
13 recall the exact substance of that  
14 conversation.  
15 Q. But it's your testimony that  
16 Mr. Rafalski told you that pain clinics  
17 are a red flag?  
18 MR. BOGLE: Object to form.  
19 THE WITNESS: I'm -- no, my  
20 testimony is I believe we  
21 discussed pain clinics as a red  
22 flag.  
23 I can't go any further than  
24 that, because I don't rightly

<p style="text-align: right;">Page 661</p> <p>1 recall all the details of that  2 conversation.  3 BY MR. MELTON:  4 Q. Is a customer that's located  5 close to a family practice with a pain  6 clinic also a red flag?  7 A. Again, I think it's  8 something that you need to look at. When  9 I say red flag, it's something that  10 raises -- it requires some additional  11 investigation and due diligence. That's  12 what I'm talking about when I mean red  13 flag.  14 Q. Have you ever heard of a  15 company called the Pharma Compliance  16 Group?  17 A. Yes, I know the Pharma  18 Compliance Group. Why?  19 Q. Are you aware that the  20 Pharma Compliance Group conducts site  21 visits for AmerisourceBergen?  22 A. No, Counselor, I wasn't.  23 Q. Are you aware that the  24 Pharma Compliance Group conducted a site</p>	<p style="text-align: right;">Page 663</p> <p>1 A. Again, if you have a  2 document that you'd like me to consider  3 and look at and talk about, I'm more than  4 happy to do that if you have it.  5 Q. No, that's okay. On Page  6 130, if you can flip to Page 130 where it  7 says "Church Square Pharmacy." Church  8 Square Pharmacy is also located in  9 Cuyahoga County; is that correct?  10 A. That is correct.  11 Q. And ABC also completed a  12 threshold review for Church Square  13 Pharmacy?  14 A. I see that, yes.  15 Q. And it's the same Ron Kline  16 who submitted the form, correct?  17 A. I believe that it is  18 correct.  19 Q. Do you know how many  20 customers ABC services in Cuyahoga  21 County?  22 A. Not off the top of my head,  23 Counselor. I can go back and look at my  24 report to see if it's in there.</p>
<p style="text-align: right;">Page 662</p> <p>1 visit of Clark Lowcost Pharmacy on behalf  2 of AmerisourceBergen?  3 MR. BOGLE: Object to form.  4 Vague and ambiguous.  5 THE WITNESS: Can you give  6 me more specifics? Because I  7 looked at a lot of documents. I  8 don't recall that in a document  9 that I saw in what I reviewed.  10 But if you have -- and, again, if  11 you have something that you'd like  12 me to review now, I'm more than  13 happy to take a look at it for  14 you.  15 BY MR. MELTON:  16 Q. So if you did rely on a  17 Pharma Compliance Site visit report, it  18 would be noted as a footnote or in the  19 reliance material in your report,  20 correct?  21 A. It would be noted in --  22 certainly in the reliance materials  23 and/or footnote, yes.  24 Q. Now --</p>	<p style="text-align: right;">Page 664</p> <p>1 Q. Was this information that  2 you requested?  3 A. Counselor, I requested a lot  4 of information. I'm sure I did request a  5 number of -- of customers. Honestly, I  6 can't tell you precisely every list of  7 requests that I made from counsel. So  8 I'm sorry.  9 Q. Have you identified any ABC  10 customers in Summit County that are  11 examples of retail pharmacy stores  12 obtaining high levels of opioids without  13 investigation or interrogation?  14 A. Again, Counselor, I can't  15 tell you because I don't remember all the  16 pharmacies that I looked at.  17 Q. But if you -- if you had  18 identified a customer in Summit County,  19 it would be noted in your report,  20 correct?  21 A. It might have been. Again,  22 I was looking for examples. I picked  23 some examples, illustrative, just like  24 you do in an audit. I can't tell you</p>

<p style="text-align: right;">Page 665</p> <p>1 without more precision and looking at 2 individual pharmacies whether it would 3 have made it into the report or not. 4 So...</p> <p>5 Q. I'll back up to Clark 6 Lowcost Pharmacy just for one second. Do 7 Pages 129 -- the section begins on page 8 129 and goes to 130.</p> <p>9 A. Correct.</p> <p>10 Q. Are Pages 129 and 130 -- 11 strike that.</p> <p>12 Do Pages 129 and 130 contain 13 all of the opinions that you intend to 14 offer regarding Clark Lowcost Pharmacy?</p> <p>15 A. Again, as we discussed 16 previously, unless there is new 17 information that comes to light that 18 warrants a review, at this moment in time 19 I believe I will be offering no more 20 opinions on these -- on this pharmacy.</p> <p>21 Q. Same question about Church 22 Square Pharmacy. Does page -- do Pages 23 130 and 131 contain all of the opinions 24 that you intend to offer regarding Church</p>	<p style="text-align: right;">Page 667</p> <p>1 AmerisourceBergen's two-part controlled 2 substance program was at best rudimentary 3 and not compliant with DEA regulatory 4 requirements"?</p> <p>5 A. Yes, I see that.</p> <p>6 Q. Is the time period covered 7 by this section prior to 2007, does that 8 mean 1997 to 2007?</p> <p>9 A. Well, we have to go to the 10 front of the report, what we said at the 11 start of the period was --</p> <p>12 Q. I think you can look in the 13 second paragraph of this section.</p> <p>14 A. Okay. I would say 1997 to 15 2007 is accurate counselor.</p> <p>16 Q. And during that time period, 17 1997 to 2007, the DEA had the authority 18 to inspect AmerisourceBergen's 19 distribution centers, correct?</p> <p>20 A. Yes. They did have that 21 authority.</p> <p>22 Q. Was the DEA in the best 23 position to determine whether ABC was 24 compliant with DEA's regulatory</p>
<p style="text-align: right;">Page 666</p> <p>1 Square Pharmacy?</p> <p>2 A. Again, unless anything new 3 comes to light that warrants me to 4 revisit it as per my report, as I state 5 upfront, it is my intention at this 6 moment not to add anything to the report 7 on this issue.</p> <p>8 Q. Do you intend to add 9 anything to the report for Summit County 10 customers?</p> <p>11 A. Again, unless I had 12 something -- again, as I said, I will 13 supplement this report as important new 14 data comes forward. It is not my 15 intention at this point to supplement my 16 report.</p> <p>17 Q. All right. Now I want to 18 ask you some questions about 19 AmerisourceBergen's order monitoring 20 program. And let's take a look at Page 21 138 of your report.</p> <p>22 A. Okay. I'm there.</p> <p>23 Q. Do you see where it says 24 11.5.1, "Prior to 2007</p>	<p style="text-align: right;">Page 668</p> <p>1 requirements?</p> <p>2 MR. BOGLE: Object to form.</p> <p>3 THE WITNESS: No, Counselor, 4 you were in the best -- ABC was in 5 the best position to determine 6 whether it was compliant with the 7 regulations. The onus is on the 8 registrant to be in compliance 9 with the regulations.</p> <p>10 BY MR. MELTON:</p> <p>11 Q. And which regulatory 12 requirements are you referring to?</p> <p>13 A. The Controlled Substances 14 Act, controlled substances regulatory 15 regulations.</p> <p>16 Q. Now, I noticed in the 17 section that Footnotes 737 738, 740, 741, 18 742, and 743 all refer to the Chris 19 Zimmerman deposition transcript; is that 20 correct?</p> <p>21 A. They all refer to that 22 deposition transcript, yes.</p> <p>23 Q. You've reviewed Chris 24 Zimmerman's deposition transcript in</p>

<p style="text-align: right;">Page 669</p> <p>1 preparing your report?</p> <p>2 A. I did review Chris</p> <p>3 Zimmerman's deposition transcript in</p> <p>4 preparing this report.</p> <p>5 Q. Did you review the</p> <p>6 deposition transcript in its entirety?</p> <p>7 A. I believe I did. I'm pretty</p> <p>8 sure I read the whole thing. But, again,</p> <p>9 I read a lot of depositions, so I can't</p> <p>10 be absolutely certain.</p> <p>11 Q. Are you aware that</p> <p>12 Mr. Zimmerman testified that he was part</p> <p>13 of the DEA's suspicious order task force</p> <p>14 in 1998?</p> <p>15 A. I vaguely recall him saying</p> <p>16 something like that in his deposition,</p> <p>17 yes.</p> <p>18 Q. Are you aware that</p> <p>19 Mr. Zimmerman testified that ABC</p> <p>20 implemented a suspicious order monitoring</p> <p>21 program in 1998 working with DEA?</p> <p>22 MR. BOGLE: Object to form.</p> <p>23 THE WITNESS: I do -- again</p> <p>24 have a general recollection of</p>	<p style="text-align: right;">Page 671</p> <p>1 recall that off the top of my</p> <p>2 head. Do you have -- again, do</p> <p>3 you have something in particular</p> <p>4 that you'd like me to look at?</p> <p>5 BY MR. MELTON:</p> <p>6 Q. Whether ABC had a suspicious</p> <p>7 order monitoring program that was</p> <p>8 approved by the DEA, would that</p> <p>9 information be germane to your evaluation</p> <p>10 of ABC's compliance program?</p> <p>11 A. Can you give me the question</p> <p>12 again, please, Counselor?</p> <p>13 Q. Whether ABC had a suspicious</p> <p>14 order monitoring program that was</p> <p>15 approved by the DEA as Mr. Zimmerman</p> <p>16 testified, would that information be</p> <p>17 germane to your evaluation of ABC's</p> <p>18 program prior to 2007?</p> <p>19 A. It would certainly be</p> <p>20 information that I would consider, but I</p> <p>21 don't see how it would affect the</p> <p>22 opinions that I've rendered in this case.</p> <p>23 Q. Let's go back to Page 132 of</p> <p>24 your report.</p>
<p style="text-align: right;">Page 670</p> <p>1 that. Again, if there's specific</p> <p>2 statements that you'd like me to</p> <p>3 look at in his deposition, I'm</p> <p>4 happy to look at them now to</p> <p>5 refresh my recollection.</p> <p>6 BY MR. MELTON:</p> <p>7 Q. But as you sit here today,</p> <p>8 you have a general recollection but could</p> <p>9 not tell me one way or the other unless</p> <p>10 you reviewed Mr. Zimmerman's transcript?</p> <p>11 A. Well, again, to be precise,</p> <p>12 you're asking me to be incredibly</p> <p>13 precise. I would need to see the</p> <p>14 document to be incredibly precise. To</p> <p>15 the best of my knowledge and</p> <p>16 recollection, I do recall something in</p> <p>17 his deposition to that effect.</p> <p>18 Q. Are you aware that</p> <p>19 Mr. Zimmerman testified that ABC</p> <p>20 implemented a suspicious order monitoring</p> <p>21 program in 1998 that was approved by the</p> <p>22 DEA?</p> <p>23 MR. BOGLE: Object to form.</p> <p>24 THE WITNESS: Again, I don't</p>	<p style="text-align: right;">Page 672</p> <p>1 A. I'm here.</p> <p>2 Q. So in the second full</p> <p>3 paragraph in the middle, do you see where</p> <p>4 it says "however"? And the statement</p> <p>5 reads, "However, the DEA was not</p> <p>6 obligated to participate in or provide</p> <p>7 input on ABC's program and doing so would</p> <p>8 have run contrary to the DEA's</p> <p>9 long-standing position that it does not</p> <p>10 endorse particular systems or programs."</p> <p>11 A. I see that.</p> <p>12 Q. Now, I note that there's no</p> <p>13 citation provided for that statement.</p> <p>14 What is the basis for that statement?</p> <p>15 A. Again, I'd have to go to the</p> <p>16 front of the report and go find you the</p> <p>17 exact citations to the controlled</p> <p>18 substances guidance. But we can page</p> <p>19 through the report if you'd like,</p> <p>20 Counsel.</p> <p>21 Q. But you would agree that</p> <p>22 there's no citation to this statement --</p> <p>23 this section.</p> <p>24 A. I would agree --</p>



<p style="text-align: right;">Page 673</p> <p>1 MR. BOGLE: Wait until he          2 finishes.          3 THE WITNESS: Sorry.          4 BY MR. MELTON:          5 Q. You would agree that there's          6 no citation to anything for this          7 statement?          8 A. I would agree there's no          9 footnote here.          10 Q. Did you speak to          11 Mr. Rafalski about this topic?          12 A. I may have. Again, as I          13 told you I don't have a detailed          14 recollection of my conversations on all          15 topics with Mr. Rafalski. We talked          16 about a lot of different topics, DEA          17 internal. But I do believe we had that          18 conversation.          19 Q. You also reviewed the          20 deposition transcript of Steve Mays in          21 preparing your report; is that correct?          22 A. Yes.          23 Q. Did you review the entire          24 transcript for Mr. Mays?</p>	<p style="text-align: right;">Page 675</p> <p>1 of documents. It would be helpful to see          2 the document.          3 Q. We'll get there. Just more          4 generically, would you agree that the          5 parties to an agreement are bound by that          6 agreement?          7 A. Again, I would agree that          8 parties sign an agreement, it's like a          9 contract if that's what you're asking,          10 Counselor. Again, I'm not sure what          11 you're asking.          12 Q. And so if there is a          13 contract, the parties are bound by that          14 contract?          15 A. That's usually the way we do          16 business.          17 (Document marked for          18 identification as Exhibit          19 Whitelaw-17.)          20 BY MR. MELTON:          21 Q. So I've marked the 2007          22 settlement agreement as Exhibit Number          23 17.          24 A. Okay.</p>
<p style="text-align: right;">Page 674</p> <p>1 A. Again, Counselor, I don't          2 remember whether I reviewed the full          3 transcript or not. I can't tell you.          4 Q. Are you aware that Mr. Mays          5 testified that ABC worked closely with          6 the DEA to develop enhancements to its          7 program in 2007?          8 MR. BOGLE: Object to form.          9 THE WITNESS: Again          10 Counselor, generically, yes. Do I          11 recall a specific reference? No.          12 BY MR. MELTON:          13 Q. Now, you also reviewed the          14 settlement agreement entered into between          15 ABDC and the DEA in 2007 in formulating          16 your report, correct?          17 A. I did.          18 Q. Would you agree that ABDC is          19 obligated to comply with the terms of the          20 2007 settlement agreement?          21 A. May I see the document again          22 to refresh my recollection again? You're          23 asking me specific questions about          24 specific documents, and I reviewed a lot</p>	<p style="text-align: right;">Page 676</p> <p>1 Q. The document is Bates          2 labeled ABDCMDL 00279854 to 865. You can          3 take a minute and familiarize yourself          4 with that.          5 A. Sure. Thank you. I see it.          6 Q. So I'd like to direct your          7 attention to Page 2 of the document where          8 it says, "Obligations of          9 AmerisourceBergen."          10 A. I see it.          11 Q. Do you see paragraph little          12 (a), where it says, "AmerisourceBergen          13 agrees to maintain a compliance program          14 designed to detect and prevent diversion          15 of controlled substances which shall          16 apply to the Orlando facility and all          17 other existing and future distribution          18 centers of AmerisourceBergen in the          19 United States"?          20 Do you see that?          21 A. Yes, I see that section.          22 Q. And then at the bottom of          23 Page 2, moving onto Page 3, Subsection C,          24 where it says, "Any material breach of</p>

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1 subsections Roman numeral II(1)(a) or (b)  
 2 of this agreement by AmerisourceBergen  
 3 after DEA restores the Orlando facility's  
 4 registration, may be a basis upon which  
 5 DEA can issue an order to show cause  
 6 seeking the revocation of the DEA  
 7 certificate of registration associated  
 8 with the distribution center whose  
 9 conduct is related to the material breach  
 10 of the agreement."  
 11 Do you see that?  
 12 A. I do see that.  
 13 Q. Aside from this 2007 issue  
 14 with the DEA, has AmerisourceBergen been  
 15 the subject of a second enforcement  
 16 action by the DEA?  
 17 A. Not to the best of my  
 18 knowledge, it has not.  
 19 Q. Has AmerisourceBergen paid  
 20 any fines relating to the diversion of  
 21 controlled substances after 2007?  
 22 A. Again, not to the best of my  
 23 knowledge.  
 24 Q. Are you aware that

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1 AmerisourceBergen didn't pay a fine in  
 2 2007 either?  
 3 A. Yes, I am aware of that.  
 4 Q. Now, on Page 3 of the  
 5 document, where it says, "Obligations of  
 6 DEA"?  
 7 A. Yep.  
 8 Q. Do you see that?  
 9 A. I do see that.  
 10 Q. And Subsection A where it  
 11 says, "The DEA shall continue to provide  
 12 diversion, prevention, and awareness  
 13 training as practicable to retail  
 14 pharmacy and industry members at  
 15 AmerisourceBergen trade shows and through  
 16 written materials"?  
 17 A. I see it.  
 18 Q. So the DEA was obligated by  
 19 this agreement to provide diversion  
 20 prevention and awareness training at ABC  
 21 trade shows; is that correct?  
 22 A. That's what it states on the  
 23 face of the document, yes.  
 24 Q. Moving onto Subsection C.

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1 Do you see where it says, "The DEA shall  
 2 conduct reviews of the functionality of  
 3 AmerisourceBergen's diversion compliance  
 4 program at up to five distribution  
 5 centers of AmerisourceBergen"?  
 6 A. Yes, I do see the -- I see  
 7 what you're reading from, yes.  
 8 Q. So AmerisourceBergen had to  
 9 pass functionality reviews by the DEA to  
 10 get their immediate suspension order  
 11 lifted; is that correct?  
 12 MR. BOGLE: Object to form.  
 13 THE WITNESS: What I see  
 14 here is simply a statement that  
 15 they shall conduct reviews of  
 16 functionality at up to five  
 17 distribution centers. That's all  
 18 I see here.  
 19 BY MR. MELTON:  
 20 Q. So DEA reviewed  
 21 AmerisourceBergen's program at up to five  
 22 distribution centers, is that fair?  
 23 MR. BOGLE: Object to form.  
 24 THE WITNESS: I can't

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1 comment on whether they did or did  
 2 not review them. I'm saying that  
 3 this was -- well, there was an  
 4 obligation that reads just like we  
 5 read the sentence back, in this  
 6 document. That's all I can state  
 7 to.  
 8 The document says what you  
 9 say it says.  
 10 BY MR. MELTON:  
 11 Q. On Pages 4 and 5 of the  
 12 document, do you see the section titled  
 13 "Joint Obligations of the Parties"?  
 14 A. Hang on a second. I see  
 15 Section 3, "Joint Obligation of Parties,"  
 16 yes.  
 17 Q. And in that section,  
 18 Subsection B where it says, "DEA and  
 19 AmerisourceBergen shall meet no less than  
 20 annually at DEA headquarters to discuss,  
 21 rely, suggestions for improvements at  
 22 AmerisourceBergen's compliance program to  
 23 detect and prevent diversion of  
 24 controlled substances; two, any concerns

<p style="text-align: right;">Page 681</p> <p>1 of the DEA related to the sales pattern 2 of controlled substances by 3 AmerisourceBergen; and three, any other 4 issues of concern to either party." 5 Do you see that? 6 A. I do see that. 7 Q. So according to this 8 section, DEA was obligated to provide 9 input on AmerisourceBergen's program at 10 annual meetings; is that correct? 11 MR. BOGLE: Object to form. 12 THE WITNESS: Counselor, 13 I -- I read it that they were -- 14 there was a meeting to talk about 15 suggestions and improvements in 16 AmerisourceBergen's compliance 17 program. That a topic of 18 discussion at those meetings would 19 be any concerns that DEA might 20 have and any other issues of 21 concerns to either of the parties. 22 Beyond that I can't comment 23 on -- 24 BY MR. MELTON:</p>	<p style="text-align: right;">Page 683</p> <p>1 A. Sure. 2 Q. Okay. Do you see on the 3 first full paragraph towards the end 4 where it says, "ABC effectively ensured 5 that the thresholds rarely would be hit, 6 thus avoiding the need to hold orders"? 7 A. Yes. 8 Q. What is the basis for that 9 statement? 10 A. Well, we can go back through 11 the whole section and talk about how they 12 were setting thresholds and size, if 13 you'd like to go, walk our way through 14 it. 15 But the size of the 16 thresholds were such, and the systems and 17 the way they were implementing the 18 process was such that it was rare that 19 these thresholds would ever be hit and 20 ever be triggered. But we can talk about 21 each of them in detail if you'd like. 22 Q. That's okay. 23 The -- is it your opinion 24 that the program implemented by</p>
<p style="text-align: right;">Page 682</p> <p>1 Q. You testified that there was 2 a meeting, but this paragraph is in the 3 section titled "Joint Obligations of the 4 Parties," correct? 5 A. It is in the section of 6 the -- of the agreement called "Joint 7 Obligations of the Parties." 8 Q. So there was a joint 9 obligation of the parties to have 10 meetings? 11 A. All I can go is -- by is 12 what the words are on the page. And the 13 words on the page say, "The DEA and 14 AmerisourceBergen shall meet no less than 15 annually at DEA headquarters." 16 Q. Setting aside this document 17 for a moment. Were you present at the 18 2007 DEA industry conference? 19 A. No, I was not. 20 Q. Were you present at the 2009 21 DEA industry conference? 22 A. Again, no, I was not. 23 Q. Let's turn to Page 143 of 24 your report.</p>	<p style="text-align: right;">Page 684</p> <p>1 AmerisourceBergen in 2007 effectively 2 ensured that the thresholds rarely would 3 be hit, thus avoiding the need to hold 4 the orders? 5 A. I'm saying -- can you 6 rephrase the question again for me 7 please? 8 Q. Is it your opinion that the 9 order monitoring program implemented in 10 2007 by AmerisourceBergen effectively 11 ensured that the thresholds rarely would 12 be hit, thus avoiding the need to hold 13 the orders? 14 A. That's what I'm saying. 15 Q. Did the DEA observe that 16 when they conducted their functionality 17 reviews at the five distribution centers 18 in 2007? 19 A. I have no idea what DEA 20 observed or did not observe. 21 Again, if you have something 22 that you'd like me to look at in 23 particular, I'm happy to examine it now. 24 Q. Let's turn to Page 144 of</p>

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1 your report.  
2 A. Okay.  
3 Q. Do you see up at the top,  
4 the last sentence of that carryover  
5 paragraph where it says, "In the eyes of  
6 the DEA's limits, ABC's basic unadjusted  
7 thresholds started out at suspicious  
8 order levels"?  
9 A. I see it.  
10 Q. Did the DEA also make that  
11 observation when they conducted the  
12 functionality reviews at five  
13 AmerisourceBergen distribution centers in  
14 2007?  
15 A. Again, Counselor, I don't  
16 know what DEA observed at those five --  
17 in those observations. But again, if you  
18 have a document you'd like me to review,  
19 I'd be happy to review them.  
20 Q. I'm just asking for your  
21 opinion.  
22 A. Without seeing a document, I  
23 cannot form an opinion.  
24 Q. Let's take a look at

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1 Page 145. It's the section that is  
2 labeled "C. OMP - Setting the Record  
3 Straight."  
4 A. Yep, I see it.  
5 Q. And it continues to  
6 Page 147?  
7 A. I see it.  
8 Q. Do you recall the documents  
9 that you reviewed that were titled  
10 "Setting the Record Straight"?  
11 A. I do recall them. And I  
12 believe they are listed here in the  
13 footnotes.  
14 Q. If you look at Page 147, the  
15 last paragraph of this section, the  
16 middle of the paragraph, it says, "I can  
17 only conclude that ABC made the change to  
18 allow its sales force to provide  
19 customers with valuable coaching on how  
20 to avoid their orders being labeled as  
21 suspicious, thereby undermining the SOM  
22 program even further."  
23 Do you see that?  
24 A. Yep.

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1 Q. Now, there's no citation  
2 after that statement. So what is the  
3 basis for that opinion or conclusion?  
4 A. The fact that you had it in  
5 the original version and then was  
6 stripped out -- the sentence, "Notifying  
7 a customer that they had been reported to  
8 the DEA or state would defeat the purpose  
9 of the monitoring program," was then  
10 stripped out of your October version,  
11 which is what we're talking about here.  
12 So the removal of that  
13 sentence, all I -- all I could conclude  
14 is you wanted to -- that sentence was  
15 removed to allow notifications to occur.  
16 Q. In the many documents that  
17 you reviewed in this case, you did not  
18 find an example of ABC's sales force  
19 providing valuable coaching to customers  
20 to avoid having their orders labeled as  
21 suspicious; is that correct?  
22 MR. BOGLE: Object to form.  
23 THE WITNESS: I looked at a  
24 lot of documents, Counselor. I

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1 can't tell you off the top of my  
2 head if I saw anything -- a  
3 particular document.  
4 Again, if there's a  
5 particular document that you'd  
6 like me to review, I would be  
7 happy to do so.  
8 BY MR. MELTON:  
9 Q. If you had seen such a  
10 document, it would be noted in your  
11 report; is that correct?  
12 A. Counselor, I noted what was  
13 relevant to formulate my opinions in the  
14 report. You're asking me a hypothetical  
15 of a hypothetical document. I can't  
16 answer that question.  
17 Q. A document that essentially  
18 proves your conclusion to be accurate  
19 would be relevant to your report,  
20 correct?  
21 A. If I saw relevant documents,  
22 I, again, more than likely would have  
23 cited to it. But again, I can't tell you  
24 unless you've got a specific document or

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<p>1 specific fact pattern, it's hard for me 2 to -- you're asking me to play what if. 3 Q. And there's nothing cited 4 after the statement that we are talking 5 about correct? 6 A. There is no footnote. 7 Q. Okay. Now continuing on 8 Page 147 where it says, "Low volume 9 accounts." 10 A. It does. 11 Q. In the second paragraph, 12 about halfway in, you write, "In other 13 words." 14 Do you see that statement? 15 A. Yes. 16 Q. The statement that begins, 17 "In other words"? 18 A. Mm-hmm. I see the 19 statement. 20 Q. Now, this statement that you 21 make here is essentially paraphrasing 22 something that you found somewhere else, 23 correct? 24 MR. BOGLE: Object to form.</p>	<p>1 did quote from the document; is that 2 right? 3 A. I did quote from the 4 document. 5 Q. Continuing on in that 6 paragraph, do you see where it says, 7 "Neither Mr. Zimmerman nor Mays in their 8 depositions could provide an alternate 9 rationale for the document"? 10 Do you see that? 11 A. I do. 12 Q. And I notice that there's 13 also no citation listed there; is that 14 correct? 15 A. There is no footnote listed 16 there, no. 17 Q. Had Mr. Zimmerman or 18 Mr. Mays been asked about this in their 19 deposition, would you have cited to the 20 testimony? 21 MR. BOGLE: Object to form. 22 THE WITNESS: Counselor, I 23 don't remember what was in those 24 depositions on this issue. I</p>
Page 690	Page 692
<p>1 THE WITNESS: Could you 2 re-ask the question again? 3 BY MR. MELTON: 4 Q. Sure. It states, "In other 5 words," and then explains what you're 6 trying to get at. So by saying "in other 7 words," it was not in the original 8 document, correct? 9 MR. BOGLE: Object to form. 10 THE WITNESS: It is my 11 reading of the document and what 12 the document actually says 13 referencing back to Footnote 789. 14 BY MR. MELTON: 15 Q. But if Document 789 actually 16 said what you say it says, you would have 17 quoted it, correct? 18 MR. BOGLE: Object to form. 19 THE WITNESS: I might have. 20 I might not have. Counselor, 21 again, you're asking me to play 22 what-if games. 23 BY MR. MELTON: 24 Q. In fact, Footnote 789, you</p>	<p>1 have -- I'd have to look at the 2 specifics. 3 BY MR. MELTON: 4 Q. Okay. Let's take a look at 5 Page 132 of your report. 6 A. I'm there. 7 Q. The third full paragraph 8 starts with, "This private face also." 9 Do you see that? 10 A. Mm-hmm. 11 Q. So in 2015, 12 AmerisourceBergen engaged FTI Consulting 13 Inc.'s health solutions practice; is that 14 correct? 15 A. That's what this report 16 says, yes. 17 Q. Is there anything wrong with 18 ABC engaging an outside consultant to 19 evaluate their anti-diversion program? 20 A. No. There's nothing wrong 21 with engaging an outside consultant, no. 22 Q. In your 30 years of 23 experience in compliance, this is the 24 type of behavior that we would like to</p>



<p style="text-align: right;">Page 693</p> <p>1 see out of companies; is that correct?</p> <p>2 A. Well, we have to take it</p> <p>3 through the whole full circle. We would</p> <p>4 like to see them engage outside</p> <p>5 consultants to improve their programs and</p> <p>6 then actually follow through and make</p> <p>7 those improvements that are recommended.</p> <p>8 That would be what we -- that's the real</p> <p>9 goal of what we're looking for.</p> <p>10 Q. You reviewed the deposition</p> <p>11 transcript of David May; is that correct?</p> <p>12 A. I did.</p> <p>13 Q. And you take issue with some</p> <p>14 of the statements that Mr. May made about</p> <p>15 the FTI findings; is that correct?</p> <p>16 A. I do.</p> <p>17 Q. Now, on Page 133 of your</p> <p>18 report at the top, the last sentence</p> <p>19 states, "Not only did Mr. May disagree</p> <p>20 with the findings, but ABC also did not</p> <p>21 implement any changes in its policies and</p> <p>22 procedures as a result of the FTI</p> <p>23 report."</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 695</p> <p>1 BY MR. MELTON:</p> <p>2 Q. It was a good guess. Do you</p> <p>3 know who Mr. May was referring to when he</p> <p>4 said "we made changes to the program"?</p> <p>5 A. I believe he was referring</p> <p>6 to ABC, but more precisely than that, no.</p> <p>7 Q. Are you aware that FTI was</p> <p>8 hired to evaluate and enhance ABC's order</p> <p>9 monitoring program in 2014?</p> <p>10 A. I don't recall seeing any</p> <p>11 documents on that. I don't.</p> <p>12 Q. Okay. Would you agree that</p> <p>13 at least as of 2016, ABC made a number of</p> <p>14 changes acting on the FTI findings?</p> <p>15 MR. BOGLE: Object to form.</p> <p>16 THE WITNESS: Let's go back.</p> <p>17 Do you have a specific section of</p> <p>18 the report that you'd like to look</p> <p>19 at?</p> <p>20 BY MR. MELTON:</p> <p>21 Q. Sure. Let's look at Page</p> <p>22 154.</p> <p>23 A. Okay.</p> <p>24 Q. Do you see in the paragraph</p>
<p style="text-align: right;">Page 694</p> <p>1 A. I do.</p> <p>2 Q. And it notes that Footnote</p> <p>3 707 details the basis for that statement,</p> <p>4 correct?</p> <p>5 A. That's what it says.</p> <p>6 Q. Footnote 707 also notes that</p> <p>7 Mr. May testified that he conducted his</p> <p>8 own review, "And we made changes to the</p> <p>9 program."</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. And it says -- in between</p> <p>13 the two quotes for Footnote 707, it says</p> <p>14 "but CF"?</p> <p>15 A. Compare.</p> <p>16 MR. BOGLE: Wait until he</p> <p>17 asks you a question.</p> <p>18 MR. MELTON: That was going</p> <p>19 to be my question.</p> <p>20 MR. BOGLE: That's fine. It</p> <p>21 may have been. I just want to</p> <p>22 make sure he's actually answering</p> <p>23 a question.</p> <p>24 MS. McCLURE: Good guess.</p>	<p style="text-align: right;">Page 696</p> <p>1 at the top of the page where it says,</p> <p>2 halfway through it says, "Therefore,</p> <p>3 despite Mr. May's contention that FTI's</p> <p>4 findings were incorrect, it appears that</p> <p>5 ABC proceeded to act on them in an effort</p> <p>6 to create 'more standardized, automated</p> <p>7 and objective processes to drive</p> <p>8 decisions and processes"?</p> <p>9 A. I do see that statement.</p> <p>10 Q. So it looks like ABC did act</p> <p>11 on the FTI findings; is that correct?</p> <p>12 A. Eventually, yes. But again</p> <p>13 we can go back and look at Mr. May's</p> <p>14 testimony and that, if I recall the date,</p> <p>15 we are talking about an event several</p> <p>16 years prior to that when those findings</p> <p>17 were -- original findings were presented</p> <p>18 to ABC.</p> <p>19 So if you give me a second.</p> <p>20 Q. I didn't ask you to go back</p> <p>21 and look at Mr. May's testimony.</p> <p>22 A. I would like to, I mean,</p> <p>23 let's be accurate.</p> <p>24 Q. Do you have Mr. May's</p>

<p style="text-align: right;">Page 697</p> <p>1 testimony?</p> <p>2 A. No, I know. Let's go back</p> <p>3 and look at the report, what I say in my</p> <p>4 report.</p> <p>5 As I recall the findings,</p> <p>6 and I can get you the date of when FTI</p> <p>7 actually made their findings, that</p> <p>8 several years had transpired. That's --</p> <p>9 Q. How about Page 132,</p> <p>10 Footnote 704?</p> <p>11 A. Yes.</p> <p>12 Q. What is the date that's</p> <p>13 listed?</p> <p>14 A. I have 2015.</p> <p>15 Q. Is there a month listed?</p> <p>16 A. August.</p> <p>17 Q. And a day?</p> <p>18 A. Yes, there's a day.</p> <p>19 Q. What is -- what is the date</p> <p>20 that is listed?</p> <p>21 A. August 25th.</p> <p>22 Q. August 25th of 2015,</p> <p>23 correct?</p> <p>24 A. Correct.</p>	<p style="text-align: right;">Page 699</p> <p>1 Q. And it's your opinion that</p> <p>2 ABC did not have a robust internal audit</p> <p>3 process; is that correct?</p> <p>4 A. That was my opinion, yes.</p> <p>5 Q. And that's your opinion</p> <p>6 because Mr. Mapes utilized the checklist;</p> <p>7 is that correct?</p> <p>8 MR. BOGLE: Object to form.</p> <p>9 THE WITNESS: No, that's not</p> <p>10 my only reason. A checklist, per</p> <p>11 se, is not the issue. There is no</p> <p>12 context around it that you'd</p> <p>13 expect to see in an audit.</p> <p>14 What were the actual</p> <p>15 transactions that were reviewed,</p> <p>16 what was the sample that was</p> <p>17 pulled, what are the management</p> <p>18 responses, what's the corrective</p> <p>19 action plan. All that is part and</p> <p>20 parcel of a formal audit program.</p> <p>21 This is more of just a quick and</p> <p>22 dirty -- as I cite, quality</p> <p>23 control checklist. It's not a</p> <p>24 real -- in my opinion, it is not a</p>
<p style="text-align: right;">Page 698</p> <p>1 Q. So if we look back at</p> <p>2 Page 154.</p> <p>3 A. 2016.</p> <p>4 Q. So a couple months --</p> <p>5 MR. BOGLE: Wait for the</p> <p>6 question.</p> <p>7 BY MR. MELTON:</p> <p>8 Q. So a couple months had</p> <p>9 passed between the FTI findings and the</p> <p>10 enhancements that were rolled out in</p> <p>11 2016?</p> <p>12 MR. BOGLE: Object to form.</p> <p>13 THE WITNESS: I don't know</p> <p>14 the exact month that they rolled</p> <p>15 out in 2016.</p> <p>16 BY MR. MELTON:</p> <p>17 Q. Take a look at Page 157.</p> <p>18 The section continues onto Page 158.</p> <p>19 A. I see it.</p> <p>20 Q. Do you recall reviewing</p> <p>21 audits of ABC's program that were</p> <p>22 conducted by Michael Mapes?</p> <p>23 A. I recall the documents that</p> <p>24 are cited here, yes.</p>	<p style="text-align: right;">Page 700</p> <p>1 real formal audit program.</p> <p>2 BY MR. MELTON:</p> <p>3 Q. Staying on Page 158. Do you</p> <p>4 see Section 11.6.1?</p> <p>5 A. I do.</p> <p>6 Q. Discussing accountability?</p> <p>7 A. I do.</p> <p>8 Q. Now, there are three</p> <p>9 individuals listed in this section; is</p> <p>10 that correct?</p> <p>11 A. There were three of the</p> <p>12 individuals listed in this section, yes.</p> <p>13 Q. And we've discussed all</p> <p>14 three of these individuals today,</p> <p>15 Mr. Zimmerman, Mr. Mays, and Mr. May; is</p> <p>16 that correct?</p> <p>17 A. Yes, they've come up today.</p> <p>18 Q. Now, you testified yesterday</p> <p>19 that holding someone accountable could</p> <p>20 range from a loss of bonus, demotion,</p> <p>21 transfer, or termination; is that</p> <p>22 correct?</p> <p>23 A. Correct.</p> <p>24 Q. Do you know whether any of</p>

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1 these three men have lost the bonus?  
2 A. I didn't see anything on the  
3 record that showed accountability.  
4 Q. Do you know whether any of  
5 these three men have been demoted?  
6 A. Again, I didn't see -- I  
7 didn't see anything in -- in my review of  
8 the records.  
9 Q. Do you know whether any of  
10 these three men have been transferred  
11 from their positions?  
12 A. Except for the fact  
13 Mr. Zimmerman is no longer chief  
14 compliance officer, again I didn't see  
15 any evidence on the record.  
16 Q. Aside from the fact that  
17 they've not been fired from  
18 AmerisourceBergen, what basis do you have  
19 to say that they've not been held  
20 accountable?  
21 A. I haven't seen anything that  
22 shows they have been accountable or shows  
23 they have been accountable.  
24 Again, Counselor, if there's

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1 something you'd like me to consider and  
2 look at I'll be happy to look at right  
3 now.  
4 Q. As you sit here today, do  
5 you intend to supplement your report with  
6 regard to AmerisourceBergen?  
7 A. Again, I reserve the right  
8 to supplement my report based on new  
9 information as it becomes available, and  
10 that's pertinent and germane to what I  
11 opined on. But I have no present plan at  
12 the moment for amending the report.  
13 Q. Are you relying today on any  
14 notes that you made to refresh your  
15 recollection regarding AmerisourceBergen  
16 in advance of testifying today?  
17 A. No. I'm testifying from  
18 my -- we went through my report.  
19 Q. Did you bring any notes with  
20 you today regarding AmerisourceBergen?  
21 A. I don't have any notes with  
22 me right now.  
23 Q. Just one more item that I  
24 want to clear up. We talked about this a

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1 little bit at the beginning, but the --  
2 we've reviewed the transcript from  
3 yesterday and the -- the -- when I  
4 thought I heard ABC, I'll represent to  
5 you that the transcript says, "I was  
6 brought in with ABC, I think at some  
7 point, to advise on antikickback and  
8 FCA."  
9 You're now saying today that  
10 your testimony did not refer to  
11 AmerisourceBergen, correct?  
12 A. I'm saying today if I said  
13 that I said I didn't recall. I was quite  
14 accurate in saying I didn't recall what  
15 I'd said yesterday. Thank you for going  
16 back.  
17 Again, I don't have any  
18 specific recollection of a specific  
19 project, no, Counselor, I don't.  
20 I thought I did. I was  
21 probably mistaken.  
22 Q. So you have no specific  
23 recollection of doing any work for ABC?  
24 A. I did not -- no specific

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1 recollection of doing work for ABC, no.  
2 I think what I would have been referring  
3 to, if I did anything, would have been a  
4 partner in the Deloitte practice would  
5 have consulted me and I would have made  
6 some statements about antikickback and --  
7 and FCA.  
8 But again, you're asking me  
9 from awhile ago, I don't rightly recall.  
10 Q. Statements about  
11 antikickback, this -- what you just  
12 mentioned --  
13 A. You had asked me --  
14 MR. BOGLE: Wait, wait,  
15 wait.  
16 BY MR. MELTON:  
17 Q. What you just mentioned  
18 about the -- the partner at Deloitte,  
19 statements about antikickback and FCA, to  
20 AmerisourceBergen?  
21 A. Again, I don't rightly  
22 recall. I was a compliance consultant in  
23 the form that I am in now within Deloitte  
24 as well. So I -- people would come to me

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1 and say well, what do you think about,  
2 what are the rules on, that's what I'm --  
3 that's what I have a vague recollection  
4 of.  
5 Q. Did you or did you not do  
6 any work --  
7 A. I did not do --  
8 MR. BOGLE: Whoa, whoa,  
9 whoa. Let him finish.  
10 THE WITNESS: I'm sorry.  
11 BY MR. MELTON:  
12 Q. Did you or did you not do  
13 any work at Deloitte regarding  
14 AmerisourceBergen?  
15 A. To the best of my knowledge,  
16 counselor, I did not bill any time to  
17 AmerisourceBergen as a client while I was  
18 at Deloitte.  
19 Q. I didn't ask you whether you  
20 billed any time. My question was whether  
21 you did any work regarding  
22 AmerisourceBergen.  
23 A. That's the best way I can  
24 tell you whether or not I did work, would

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1 be -- if I did work, it would have been  
2 billed time. And I don't recall billing  
3 any time to AmerisourceBergen as an  
4 account.  
5 Q. So if you did not bill time  
6 to AmerisourceBergen, then you did not do  
7 work for AmerisourceBergen, correct?  
8 A. As far as I -- it certainly  
9 would have been unbillable time. Like I  
10 said, I don't rightly recall. I'm sorry.  
11 It's been a while.  
12 Q. So you don't know whether  
13 you did any work for AmerisourceBergen?  
14 MR. BOGLE: Object to form.  
15 Asked and answered.  
16 THE WITNESS: I will answer  
17 the question the best I can again,  
18 Counselor. I did not bill any  
19 time to the AmerisourceBergen  
20 account that I recollect doing  
21 when I was at Deloitte.  
22 MR. MELTON: At this time  
23 I'm going to pass the witness.  
24 Let's go off the record.

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1 THE VIDEOGRAPHER: Going off  
2 the record. 11:31 a.m.  
3 (Short break.)  
4 THE VIDEOGRAPHER: We are  
5 back on the record at 11:46 a.m.  
6 - - -  
7 EXAMINATION  
8 - - -  
9 BY MR. HYNES:  
10 Q. Good morning, Dr. Whitelaw.  
11 My name is Paul Hynes. We met off the  
12 record. I represent CVS in this case.  
13 First, sir, do you have any  
14 opinions about CVS that are not in your  
15 report or your supplemental report?  
16 A. No, sir. My report is, and  
17 supplemental are part of the record.  
18 Q. Okay. And do you have any  
19 intention currently to offer any opinions  
20 about CVS that are not in either report?  
21 A. I have no current intentions  
22 to do that.  
23 Q. Okay. And do your reports  
24 cite all the evidence that you're relying

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1 on to support your opinions about CVS?  
2 A. With the exception of my  
3 30 years' experience of being a  
4 compliance officer and -- but if you're  
5 looking for documents, yes.  
6 Q. Okay. And do you have any  
7 intention currently to rely on any  
8 evidence not cited in your reports to  
9 support your opinions about CVS?  
10 A. Again, other than my  
11 30 years' experience and my conversations  
12 that we talked about in depth with  
13 Mr. Rafalski, no. But those are cited --  
14 that conversation is cited in the report  
15 too, so...  
16 Q. I want to talk about your  
17 review of CVS documents. Did you follow  
18 the same process for CVS that you  
19 described yesterday that you requested  
20 certain categories of documents from  
21 plaintiffs' counsel?  
22 A. Yes, sir, I did.  
23 Q. I want to turn to pages 276  
24 and 77 of your report. It's in the

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<p>1 appendices. 2 A. Okay. 3 Q. You list there 16 CVS 4 depositions. Did you review all of those 5 deposition transcripts or just portions? 6 A. I can't tell you at this 7 point whether I reviewed all or portions 8 at this point, considering the number of 9 deposition transcripts that I worked 10 with. 11 Q. Can you tell me whether you 12 reviewed the entirety of any of those 13 depositions? 14 A. I believe I reviewed the 15 entirety of some of them, but I can't 16 tell you which ones right off the top of 17 my head right now. 18 Q. Okay. Did you request any 19 depositions from counsel that were not 20 provided to you? 21 A. I -- everything I requested 22 from counsel was provided for me if they 23 could find it in their files. 24 Q. Okay. And did you watch any</p>	<p>1 A. No, they did not. 2 Q. Any sentence in the CVS 3 sections of your reports? 4 A. No. I drafted everything. 5 Q. Did they provide any edits 6 to the CVS sections of your reports? 7 A. No they didn't provide 8 edits. They may have provided comments 9 where I was factually incorrect or had a 10 wrong Bates stamp number or something 11 along those lines, but no. 12 Q. Were those comments conveyed 13 to you orally or in written form? 14 A. Probably both. 15 Q. Okay. So is it your 16 testimony, sir, that not a single word in 17 the CVS sections of your report came from 18 plaintiffs' counsel? 19 A. It's my testimony I wrote 20 this report soup to nuts, yes. 21 Q. Did plaintiffs' counsel 22 provide you with a list or outline of 23 opinions to give about CVS? 24 A. Absolutely not.</p>
Page 710	Page 712
<p>1 videos of the CVS depositions listed in 2 your appendices? 3 A. No, I reviewed the written 4 transcripts. 5 Q. Sir, did you prepare any 6 notes to possibly be used to refresh your 7 recollection during this deposition 8 related to CVS? 9 A. Yes, I did. 10 Q. Okay. I would just ask that 11 if you do use those notes, you tell me. 12 Is that fair? 13 A. That -- ask the gentleman to 14 my left. 15 MR. BOGLE: Yes. If he uses 16 them, yeah, of course, yes. 17 BY MR. HYNES: 18 Q. I want to talk about how you 19 drafted your report. Did plaintiffs' 20 counsel draft any of the CVS sections of 21 your reports? 22 A. No, they did not. 23 Q. Did they draft any of the 24 CVS paragraphs of your reports?</p>	<p>1 Q. A list or outline of CVS 2 issues to consider? 3 A. No. That I recall, no. 4 Q. A list or outline of CVS 5 facts to address? 6 A. Again, not that I recall. 7 Q. Sir, I want you to turn to 8 Page 161 of your report, please. 9 A. I'm here. 10 Q. Okay. And it's the last 11 sentence above Section 12.3. And it's 12 actually the second-to-last line going 13 onto the last line there. You state, "If 14 the mode model had a remedial level, I 15 would place a CVS program there." 16 Do you see that? 17 A. I do. 18 Q. When you say the CVS 19 program, are you referring to the CVS SOM 20 program? 21 A. I'm referring to the CVS 22 anti-diversion program, of which SOM is a 23 key component of it. 24 Q. Okay. Have you evaluated</p>



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1 any other CVS anti-diversion programs?  
2 MR. BOGLE: Object to form.  
3 THE WITNESS: I'm not sure I  
4 understand.  
5 BY MR. HYNES:  
6 Q. Have you evaluated any CVS  
7 anti-diversion programs other than the  
8 CVS SOM program?  
9 MR. BOGLE: Object to form.  
10 THE WITNESS: Again, I think  
11 I have covered this before. The  
12 focus was on SOM. They all fit  
13 together. I focused on -- I did  
14 focus on suspicious order  
15 monitoring. In the context of a  
16 broader anti-diversion program, in  
17 the context of a broader corporate  
18 compliance program.  
19 BY MR. HYNES:  
20 Q. Okay. So you didn't review  
21 any documents related to CVS's theft and  
22 loss reporting?  
23 A. No, I did not.  
24 Q. Or any documents related to

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1 its pharmacy-level anti-diversion  
2 programs?  
3 A. No, I did not.  
4 Q. Okay. The model that you  
5 discuss here, have you ever, in all the  
6 times that you've used that model, found  
7 an SOM program to score above the  
8 foundational level?  
9 MR. BOGLE: For clarity, are  
10 you talking about Figure 2? When  
11 you say model? I just want to  
12 make sure --  
13 MR. HYNES: Yeah.  
14 THE WITNESS: I don't know  
15 what model you're talking about.  
16 BY MR. HYNES:  
17 Q. The -- yeah, Figure 2.  
18 Where -- the one in front of you there.  
19 This model right here.  
20 A. That model?  
21 Q. Yeah.  
22 A. And all the time that I've  
23 used it for an SOM?  
24 Q. Yeah.

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1 A. Applied to an SOM program  
2 alone?  
3 Q. Yes, have you ever found,  
4 when you applied it to a SOM program,  
5 have you found such a program to score  
6 above the foundational level?  
7 A. No, I have not.  
8 Q. Before you were engaged in  
9 this case, had you ever used this model  
10 to evaluate an SOM program?  
11 A. No, I had not. But it is a  
12 standard compliance maturity model that  
13 I've used to evaluate compliance  
14 programs.  
15 Q. But not an SOM program  
16 before you were --  
17 A. Not an SOM --  
18 Q. -- engaged in this case?  
19 A. -- program, per se.  
20 Q. I want to turn to --  
21 MR. BOGLE: Just wait until  
22 he finishes.  
23 BY MR. HYNES:  
24 Q. -- CVS's distribution

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1 business. You know that CVS is a  
2 national chain pharmacy, correct?  
3 A. Yes, sir, I do.  
4 Q. Okay. And I think you state  
5 in your report, it has 9,800 retail  
6 pharmacies. Page 159.  
7 A. I believe that's --  
8 Q. Approximately.  
9 A. Approximately. That number  
10 rings a bell.  
11 Q. I'm not trying to test you  
12 on that.  
13 Are -- are you aware how  
14 many retail pharmacies CVS has in  
15 Cuyahoga and Summit Counties?  
16 A. Not off the top -- the  
17 number? I don't have a hard number off  
18 the top of my head.  
19 Q. Is that something you looked  
20 into when you were evaluating CVS's SOM  
21 program?  
22 A. Again, I evaluated a lot of  
23 different things in the SOM program. And  
24 I may have looked into it. Again, I

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1 can't rightly recall. It doesn't -- I  
2 don't have a recollection of it for you.  
3 Q. Okay. And are you aware of  
4 how many CVS warehouses distributed to  
5 CVS retail pharmacies in Cuyahoga and  
6 Summit County?  
7 A. My understanding, based on  
8 my review, was it was in the -- the  
9 Indianapolis distribution center was  
10 distributing into Summit and Cuyahoga  
11 County. That's what I have.  
12 Q. Okay. And are you aware  
13 that like Walgreens, CVS only distributes  
14 to itself, to -- to its own pharmacies?  
15 A. Yeah, I believe that was  
16 what was noted in my report.  
17 Q. So it doesn't distribute to  
18 pain clinics, correct?  
19 A. I know it distributes to its  
20 own pharmacies.  
21 Q. Okay. So you -- you are  
22 aware then that it doesn't distribute to  
23 pain clinics?  
24 A. If they are not owned by

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1 CVS, I'm aware that they only distribute  
2 to CVS entities.  
3 Q. Okay. Are you familiar with  
4 the pharmaceutical drugs distributed by  
5 CVS warehouses?  
6 MR. BOGLE: Object to form.  
7 Vague and overbroad.  
8 THE WITNESS: Can you be  
9 more specific?  
10 BY MR. HYNES:  
11 Q. Are you aware that CVS does  
12 not distribute Schedule II controlled  
13 drugs?  
14 A. Does not.  
15 Q. Yes.  
16 A. Yes, I am aware of that.  
17 Q. And are you aware that of  
18 the prescription opioids at issue in this  
19 case, CVS only distributed hydrocodone  
20 combination products?  
21 A. Yes, I am aware of that.  
22 Q. All right. I'm going to  
23 refer to those as HCPs throughout the  
24 day. It's just easier to say.

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1 A. Okay.  
2 Q. So CVS produced  
3 transactional data in this case showing  
4 all of its shipments of controlled and  
5 noncontrolled drugs to Cuyahoga and  
6 Summit County. Have you reviewed that  
7 transactional data?  
8 A. No, I have not reviewed all  
9 of that transactional data.  
10 Q. Have you reviewed any of it?  
11 A. Again, I don't recall.  
12 Q. Okay. So is it fair to say  
13 you're not familiar with the percentage  
14 of shipments CVS made to Cuyahoga and  
15 Summit County that were controlled drugs  
16 versus noncontrolled drugs?  
17 A. I would say that if it's  
18 not -- not referenced in the report, I  
19 don't recall it.  
20 Q. And you are also not aware  
21 of the percentage of shipments that CVS  
22 made to those two counties that were HCPs  
23 versus other kinds of drugs?  
24 A. Again, if it's not in the

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1 report I don't recall it.  
2 Q. Okay. Did you make a  
3 determination whether any of the  
4 shipments in the transactional data that  
5 CVS made to those two counties were  
6 diverted?  
7 MR. BOGLE: Object to form.  
8 THE WITNESS: I'll go back  
9 to where -- what I was asked to  
10 look at.  
11 BY MR. HYNES:  
12 Q. Okay.  
13 A. I was asked to look at the  
14 SOM program, anti-diversion program,  
15 corporate compliance program, from a  
16 process, procedure, and following it  
17 standpoint.  
18 That was what I was asked to  
19 do, and that's what this report covers.  
20 Q. Okay. That's -- that's  
21 fair. I just want to make sure then, you  
22 didn't -- you didn't take it a step  
23 further and determine whether any HCPs  
24 distributed by CVS in the Cuyahoga and

<p style="text-align: right;">Page 721</p> <p>1 Summit Counties were diverted?</p> <p>2 A. I stayed and looked at it</p> <p>3 from a corporate compliance program,</p> <p>4 effectiveness setup, and whether it was</p> <p>5 followed, and that's as far as my report</p> <p>6 goes.</p> <p>7 Q. Okay. Could you answer -- I</p> <p>8 don't want to be difficult. I would like</p> <p>9 a yes or no answer. It's a pretty simple</p> <p>10 question.</p> <p>11 Did you determine whether</p> <p>12 any of those shipments were diverted?</p> <p>13 A. No, sir. I did not --</p> <p>14 Q. Thank you.</p> <p>15 A. -- determine that.</p> <p>16 Q. Sir, you discuss -- let's</p> <p>17 get to the page. Let's turn to Pages 161</p> <p>18 and 162 of your report.</p> <p>19 A. Okay.</p> <p>20 Q. You discuss there two CVS</p> <p>21 pharmacies in Indiana. One in Vincennes,</p> <p>22 Indiana, and one in Columbus, Indiana.</p> <p>23 A. Mm-hmm.</p> <p>24 MR. BOGLE: Make sure you</p>	<p style="text-align: right;">Page 723</p> <p>1 Q. So you didn't -- you didn't</p> <p>2 see any due diligence files related to</p> <p>3 these two pharmacies?</p> <p>4 A. I did not.</p> <p>5 Q. Okay. And you are aware,</p> <p>6 and I just said it. But you are aware</p> <p>7 these pharmacies are located in Indiana,</p> <p>8 right?</p> <p>9 A. I am aware that these two</p> <p>10 pharmacies are located in Indiana. But</p> <p>11 again CVS, like all the other defendants</p> <p>12 in this case, were running national --</p> <p>13 Q. That's fair. That --</p> <p>14 A. -- programs.</p> <p>15 Q. But I just want to get to</p> <p>16 your point about due diligence files.</p> <p>17 And this case involves Cuyahoga and</p> <p>18 Summit Counties. Okay?</p> <p>19 A. I'm aware of that.</p> <p>20 Q. Are you aware that the</p> <p>21 discovery links in this case only</p> <p>22 obligated CVS to produce due diligence</p> <p>23 files related to Cuyahoga and Summit</p> <p>24 Counties?</p>
<p style="text-align: right;">Page 722</p> <p>1 say yes or no.</p> <p>2 THE WITNESS: Yes, I do.</p> <p>3 BY MR. HYNES:</p> <p>4 Q. Sir, you cite the volume of</p> <p>5 HCP tablets distributed to those stores</p> <p>6 between January 2012 and October 2013,</p> <p>7 correct?</p> <p>8 A. I do.</p> <p>9 Q. And that's based on an</p> <p>10 e-mail that a DEA agent sent to a CVS</p> <p>11 employee, correct?</p> <p>12 A. Correct.</p> <p>13 Q. Did you go back and --</p> <p>14 strike that.</p> <p>15 Did you consider any other</p> <p>16 data about these stores such as the</p> <p>17 overall volume of controlled substances</p> <p>18 that they dispensed?</p> <p>19 A. What I considered, or at</p> <p>20 least asked for, was additional evidence</p> <p>21 of due diligence by CVS on these</p> <p>22 particular stores in response to this</p> <p>23 query about dosages. And I didn't really</p> <p>24 see an effective due diligence file.</p>	<p style="text-align: right;">Page 724</p> <p>1 A. I'm not sure I knew exactly</p> <p>2 what the complete limits of your</p> <p>3 discovery requests were. Again, I</p> <p>4 requested due diligence files on these --</p> <p>5 on these stores and I didn't see</p> <p>6 anything.</p> <p>7 Q. So you are not aware that</p> <p>8 CVS did not have an obligation to produce</p> <p>9 due diligence files related to</p> <p>10 distribution to these stores?</p> <p>11 A. Not that I can rightly</p> <p>12 recall.</p> <p>13 Q. That's not something</p> <p>14 plaintiffs' counsel told you?</p> <p>15 A. Again, I don't recall.</p> <p>16 Q. Okay. That's fine.</p> <p>17 Sir, are you aware of any</p> <p>18 HCPs dispensed by these two stores that</p> <p>19 ended up in Cuyahoga and Summit Counties?</p> <p>20 A. No, I didn't. Again, it was</p> <p>21 outside the scope of this report.</p> <p>22 Q. Okay. On Page 162 you</p> <p>23 discuss three corporate integrity</p> <p>24 agreements that CVS entered into with the</p>

<p style="text-align: right;">Page 725</p> <p>1 Office of Inspector General for HHS.          2 A. I do.          3 Q. And you'd agree, sir, that          4 those agreements are not related to CVS's          5 SOM system?          6 A. Yes. As -- as stated in the          7 report.          8 Q. Yeah. You state in your          9 report that they are not even related to          10 controlled substances, correct?          11 A. That is correct.          12 Q. And on 162 going over to          13 163, you discuss three settlement          14 agreements that CVS entered into with          15 DEA; is that right?          16 A. That is correct.          17 Q. And the first one relates to          18 sales of PSE, pseudoephedrine products.          19 A. It does.          20 Q. In California and Nevada in          21 2007 and 2008, correct?          22 A. Correct.          23 MR. BOGLE: Just make sure          24 he's totally done. Give him maybe</p>	<p style="text-align: right;">Page 727</p> <p>1 pharmacies in Oklahoma?          2 A. To the best of my          3 recollection, yes.          4 Q. Okay. Thanks. And the          5 other one relates to the theft and loss          6 reporting by CVS retail pharmacies in two          7 counties in New York; is that correct?          8 A. That is correct.          9 Q. Okay. So neither of those          10 settlements involved CVS's SOM program,          11 did they?          12 A. No.          13 MR. BOGLE: Object to form.          14 BY MR. HYNES:          15 Q. And neither involved CVS          16 warehouses in Indianapolis, Indiana --          17 A. To the best --          18 Q. -- or Chemung, New York?          19 A. To the best of my knowledge,          20 no.          21 Q. And neither involved CVS          22 retail pharmacies in Cuyahoga and Summit          23 Counties?          24 A. Again to the best of my</p>
<p style="text-align: right;">Page 726</p> <p>1 a second to make sure he's totally          2 done.          3 MR. HYNES: That's fine.          4 That's fine.          5 BY MR. HYNES:          6 Q. So those agreements did not          7 involve controlled substances, did they,          8 that agreement?          9 A. They -- that agreement did          10 not.          11 Q. And it did not involve          12 Cuyahoga and Summit Counties?          13 A. No, sir, it did not.          14 Q. And then you talk about two          15 other agreements. One relates to          16 recordkeeping violations by CVS retail          17 pharmacies in Oklahoma, correct?          18 A. I do.          19 Q. And the other -- but is that          20 what one of them relates to?          21 A. I do talk about an Oklahoma          22 case, yes.          23 Q. Okay. And that involves a          24 recordkeeping violations by CVS retail</p>	<p style="text-align: right;">Page 728</p> <p>1 knowledge, no, they did not.          2 Q. Okay. Sir, are you aware          3 that CVS has never entered into a          4 settlement agreement with DEA related to          5 its SOM program for controlled          6 substances?          7 A. I am aware.          8 Q. Okay. And you're aware that          9 CVS has never paid a fine to DEA related          10 is its SOM program for controlled          11 substances?          12 A. Yes.          13 Q. And you're aware that CVS          14 has never been involved in any litigation          15 with DEA related to its SOM program for          16 controlled substances?          17 A. At least what litigation          18 that I know about that's on the public          19 record, yes, I would agree with your          20 statement.          21 Q. Did you -- okay. And did          22 you go look at the public record to          23 investigate --          24 A. I did.</p>

<p style="text-align: right;">Page 729</p> <p>1 Q. -- CVS litigation?</p> <p>2 MR. BOGLE: Wait until he's</p> <p>3 done.</p> <p>4 BY MR. HYNES:</p> <p>5 Q. You answered. That's okay.</p> <p>6 A. I did.</p> <p>7 MR. BOGLE: You're going to</p> <p>8 get strangled by the court</p> <p>9 reporter here in a minute.</p> <p>10 THE WITNESS: I know she's</p> <p>11 going to kill me.</p> <p>12 BY MR. HYNES:</p> <p>13 Q. Apologize to her, not to me.</p> <p>14 THE WITNESS: Sorry,</p> <p>15 Michelle.</p> <p>16 BY MR. HYNES:</p> <p>17 Q. All right. Let's talk about</p> <p>18 the automated SOM system that you</p> <p>19 discussed in your -- in the CVS section</p> <p>20 of your report.</p> <p>21 Are you aware that that</p> <p>22 system was designed by a company called</p> <p>23 Cegedim Dendrite?</p> <p>24 A. Can we go to the section of</p>	<p style="text-align: right;">Page 731</p> <p>1 different -- actually many different DEA</p> <p>2 registrants?</p> <p>3 A. I'm -- I'm aware they had a</p> <p>4 DEA SOM program -- practice. I would</p> <p>5 assume that they designed multiple</p> <p>6 systems for multiple clients, but it's an</p> <p>7 assumption.</p> <p>8 Q. Okay. And are you also</p> <p>9 aware that the company was -- or at least</p> <p>10 its DEA compliance division was run by</p> <p>11 Ronald Buzzeo?</p> <p>12 A. I'm familiar with the name,</p> <p>13 yes.</p> <p>14 Q. You are. Have you ever met</p> <p>15 Mr. Buzzeo?</p> <p>16 A. This entire -- Counselor,</p> <p>17 you're seeing a puzzled look because I've</p> <p>18 gone to lots of conferences over 30</p> <p>19 years. It's entirely possible our paths</p> <p>20 have crossed. I don't rightly recall the</p> <p>21 man, but --</p> <p>22 Q. Okay.</p> <p>23 A. -- it's entirely possible</p> <p>24 that we shook hands at some point at some</p>
<p style="text-align: right;">Page 730</p> <p>1 the report --</p> <p>2 Q. Yeah.</p> <p>3 A. -- that you're referring to?</p> <p>4 Q. Sure.</p> <p>5 A. Where are you referring to,</p> <p>6 would be helpful to know.</p> <p>7 Q. You discuss throughout most</p> <p>8 of the --</p> <p>9 A. I guess, is there a</p> <p>10 particular section you'd like to --</p> <p>11 Q. No, I don't have one in mind</p> <p>12 right now. I'm just --</p> <p>13 A. Okay. That's all right.</p> <p>14 Q. I have some very general</p> <p>15 questions about the system. Are you</p> <p>16 aware that it was designed by a company</p> <p>17 called Cegedim Dendrite?</p> <p>18 A. Yes, sir, I am.</p> <p>19 Q. Are you familiar with that</p> <p>20 company?</p> <p>21 A. Yes, I am familiar with the</p> <p>22 company.</p> <p>23 Q. Are you aware that it</p> <p>24 designed SOM systems for several</p>	<p style="text-align: right;">Page 732</p> <p>1 conference.</p> <p>2 Q. Okay. Conferences. Sir,</p> <p>3 the DEA held distributor conferences in</p> <p>4 2013, '15, and '16. Did you attend any</p> <p>5 of those?</p> <p>6 A. No, I did not.</p> <p>7 Q. Okay. And they also -- the</p> <p>8 DEA also held national conferences on</p> <p>9 pharmaceutical and chemical diversion</p> <p>10 every year from 2008 to '12 and then 2014</p> <p>11 and '17. Did you attend any of those?</p> <p>12 A. No, I did not.</p> <p>13 Q. Okay. And then it also</p> <p>14 held -- it's held several practitioner</p> <p>15 awareness conferences since 2018. Have</p> <p>16 you attended any of those?</p> <p>17 A. No.</p> <p>18 Q. Okay. And going back to</p> <p>19 Mr. Buzzeo. Are you aware that he</p> <p>20 previously worked at the DEA?</p> <p>21 A. Yes, I am aware of that.</p> <p>22 Q. Do you know what his</p> <p>23 position was?</p> <p>24 A. No, sir, I don't recall.</p>



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1 Q. Okay. If I told you that he  
2 was the former deputy director of the  
3 DEA's office of diversion control, do you  
4 have any reason to think that's not  
5 accurate?  
6 A. I don't have any reason to  
7 dispute it one way or another. I have no  
8 opinion.  
9 Q. Okay. All right. Thank  
10 you.  
11 We're going to talk about  
12 this. So I'm just going to call it the  
13 Buzzeo system. It's a lot easier to say  
14 than Cegedim Dendrite. Is that all -- is  
15 that fair? That's what we've called it  
16 in our depositions?  
17 A. That's fair.  
18 Q. Okay. Are you familiar with  
19 the algorithm used by the Buzzeo system?  
20 A. Yes, I'm familiar with the  
21 documents that I reviewed that discuss  
22 the algorithm from the Buzzeo system.  
23 Q. Are you familiar with how  
24 the algorithm works?

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1 A. In general terms, yeah. I'm  
2 not a statistician.  
3 Q. Okay. So could you explain  
4 to me the coefficients and the math  
5 behind it?  
6 A. Absolutely not.  
7 Q. Okay. Did you try to learn  
8 the math behind it?  
9 A. No. I'm not a statistician.  
10 Q. Okay. Then, is it fair to  
11 say that you're not giving an opinion  
12 about the sufficiency of the algorithm  
13 itself, just focused on the algorithm?  
14 A. I am not giving an opinion  
15 on the sufficiency of the algorithm  
16 itself. What I was talking about was how  
17 the algorithm ended up being used and was  
18 put into practice and process.  
19 Q. Yeah. And we'll talk about  
20 that. Okay. And are you familiar with  
21 the daily report that was generated by  
22 the algorithm?  
23 A. Well, I guess we have to be  
24 specific about what period of time. Are

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1 you referring to the IRR?  
2 Q. Yes, the IRR?  
3 A. Which -- which report --  
4 Q. Yeah, the IRR.  
5 A. Yes, I am familiar with the  
6 IRR report.  
7 Q. Thank you. And did you  
8 review any IRRs?  
9 A. I reviewed IRRs, yes.  
10 Q. How many?  
11 A. I don't remember.  
12 Q. How did you select the ones  
13 you reviewed?  
14 A. I asked for IRRs. Please  
15 submit -- you know, give me IRR reports  
16 to review. I didn't --  
17 Q. And counsel provided those  
18 to you?  
19 A. Counsel provided me with  
20 what they had.  
21 Q. You don't know how many?  
22 A. I don't recall.  
23 Q. Okay. Do you know if you  
24 reviewed -- these were used from

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1 roughly -- I think the ones that we were  
2 able to locate and produce from 2010  
3 through early 2014. Did you review IRRs  
4 from, you know, each year or --  
5 A. Counsel --  
6 Q. -- a representative sample?  
7 MR. BOGLE: Wait until he's  
8 done.  
9 THE WITNESS: I reviewed the  
10 sample. I can't tell you how I  
11 picked the sample. And I can't  
12 tell you what I remember from the  
13 sample at this point in time. I  
14 reviewed a lot of documents.  
15 BY MR. HYNES:  
16 Q. Okay. Page 167 of your  
17 report talks about --  
18 A. Which page, please?  
19 Q. 167.  
20 A. I'm sorry.  
21 Q. No, no. I talk fast. You  
22 talk about an IRR for the Indianapolis  
23 distribution center from November 30,  
24 2010.

<p style="text-align: right;">Page 737</p> <p>1 Do you see that?</p> <p>2 A. I do.</p> <p>3 Q. Do you recall reviewing that</p> <p>4 IRR?</p> <p>5 A. I do actually.</p> <p>6 Q. Okay. And is it possible</p> <p>7 that that was the only IRR you reviewed?</p> <p>8 A. I could go back to my</p> <p>9 reliance materials and try to drag --</p> <p>10 drag it out for you. I don't remember.</p> <p>11 Q. Okay. Okay. Then I'll move</p> <p>12 on. Thank you.</p> <p>13 Can you tell me what the</p> <p>14 average size of an IRR is? Like, how</p> <p>15 many -- how many pages are typically in</p> <p>16 an IRR?</p> <p>17 A. Again, I can tell you what I</p> <p>18 reviewed and the pages that I got from</p> <p>19 that. Again, I can't tell you what an</p> <p>20 average number of pages. I didn't do an</p> <p>21 average page count.</p> <p>22 Q. Okay. Did you look to see</p> <p>23 on average how many HCP orders were in an</p> <p>24 IRR?</p>	<p style="text-align: right;">Page 739</p> <p>1 IRR. I examined the IRR. I made an</p> <p>2 effort to look at the fields. Beyond</p> <p>3 that I can't tell you. I -- you are</p> <p>4 asking for precision I can't give you.</p> <p>5 But again, I'm happy to look at a</p> <p>6 document if you have one.</p> <p>7 Q. Okay. Sitting here today,</p> <p>8 you can't tell me what for example, the</p> <p>9 PZ scores are, or the -- the trend above</p> <p>10 month or the trend slip. You can't tell</p> <p>11 me what those data fields --</p> <p>12 A. No, I cannot tell you.</p> <p>13 Q. Okay. Sir, I'll move to</p> <p>14 Page 173 of your report.</p> <p>15 A. Which page, please?</p> <p>16 Q. 173.</p> <p>17 A. Okay.</p> <p>18 Q. And I want to draw your</p> <p>19 attention -- I'll let you get there</p> <p>20 first. It's the first full paragraph on</p> <p>21 that page.</p> <p>22 A. Okay.</p> <p>23 Q. And it's the -- the second</p> <p>24 to last sentence in that paragraph. You</p>
<p style="text-align: right;">Page 738</p> <p>1 A. Again, I can remember</p> <p>2 reviewing the IRR. I can't be more</p> <p>3 specific at this point in time.</p> <p>4 Q. Okay. Are you familiar with</p> <p>5 the data that's presented for an order on</p> <p>6 the IRR?</p> <p>7 A. Again, I've looked at an</p> <p>8 IRR. Can I recall the exact fields that</p> <p>9 are on there? No. But if you have a</p> <p>10 document you'd like to show me,</p> <p>11 counselor, I'm happy to look at it again.</p> <p>12 Q. So you can't tell me what</p> <p>13 the binary day related to, the binary day</p> <p>14 field related to?</p> <p>15 A. As I said, I don't remember</p> <p>16 the specifics fields on the IRR. Again,</p> <p>17 if there's a document you'd like me to</p> <p>18 look to, I'll be happy to look to it.</p> <p>19 Q. I don't have one with me</p> <p>20 here, sir. So I'm sorry. I just want</p> <p>21 to -- did you make any effort to</p> <p>22 understand the various different data</p> <p>23 fields presented on the IRR?</p> <p>24 A. Counselor, I looked at the</p>	<p style="text-align: right;">Page 740</p> <p>1 write, "If an order is more likely to fit</p> <p>2 the DEA's definition of a suspicious</p> <p>3 order, the CCS-SOMS program, 'pends' or</p> <p>4 flags an order that may be suspicious."</p> <p>5 Do you see that?</p> <p>6 A. I do see that.</p> <p>7 Q. Okay. And then moving down</p> <p>8 under Section 3, "Item Review Reports."</p> <p>9 I want to draw your attention to the</p> <p>10 first sentence, and -- and after the</p> <p>11 comma you write, "The IRR became the</p> <p>12 vehicle by which pending orders (i.e.,</p> <p>13 orders that scored above .15 and thus</p> <p>14 were suspicious)."</p> <p>15 So I just -- if you can help</p> <p>16 me.</p> <p>17 Is it -- is it your</p> <p>18 recollection or your view that an order</p> <p>19 flagged on the IRR was an order that may</p> <p>20 be suspicious and needed to be</p> <p>21 investigated, or -- or it was an order</p> <p>22 that was suspicious?</p> <p>23 A. What I'm saying is that if</p> <p>24 the order flagged from the algorithm is</p>

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1 suspicious in the sense it needs further  
 2 investigation.  
 3 Q. You're not saying that every  
 4 order that flags on the IRR has to be  
 5 reported to DEA?  
 6 MR. BOGLE: Object to form.  
 7 THE WITNESS: Can you be  
 8 more precise?  
 9 BY MR. HYNES:  
 10 Q. Yes.  
 11 You're -- you're familiar  
 12 with the requirement that a DEA  
 13 registrant report a suspicious order to  
 14 DEA?  
 15 A. Yes.  
 16 Q. Correct?  
 17 A. I am familiar with it.  
 18 Q. Okay. So is it your opinion  
 19 that CVS was obligated to report to DEA  
 20 every order that flagged on an IRR?  
 21 A. I believe my opinion has  
 22 been consistent throughout, which is any  
 23 order that flagged on an IRR needed  
 24 further investigation to determine

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1 whether the red flags, that fact it  
 2 flagged on the system, did -- was  
 3 something that could be resolved or not  
 4 resolved, and if it can't be resolved, it  
 5 needs to be reported to the DEA.  
 6 But at the same time, those  
 7 orders should be held and not shipped  
 8 until you come to a final determination.  
 9 Q. Okay. Staying on page --  
 10 I'm finding a page number. Give me one  
 11 second.  
 12 Sir, you are familiar with  
 13 CVS raising the score upon which an order  
 14 would flag on the IRR from .15 to .65; is  
 15 that correct?  
 16 A. I'm -- I am -- are you  
 17 looking at a particular section we want  
 18 to talk about?  
 19 Q. Yeah.  
 20 A. Please.  
 21 Q. I'm looking at the  
 22 Section 4 -- going from 175 to 176.  
 23 A. Okay. Yes, I am familiar  
 24 with that happening twice.

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1 Q. Okay. I want to discuss the  
 2 first paragraph under Section 4, second  
 3 sentence. You say --  
 4 A. I'm sorry. First paragraph?  
 5 Q. First paragraph under  
 6 Section 4, in the second sentence of that  
 7 paragraph. 175.  
 8 MR. BOGLE: You are on the  
 9 wrong page.  
 10 THE WITNESS: Thank you.  
 11 BY MR. HYNES:  
 12 Q. You write, "In other words,  
 13 rather than increase headcount to support  
 14 the SOM program or alternatively taking  
 15 an in-depth look at its pharmacies'  
 16 ordering practice to determine what might  
 17 be the root cause of the problem, CVS  
 18 simply altered the system to force the  
 19 designed" -- "the desired outcome even  
 20 though doing so compromised the  
 21 effectiveness of the CCS-SOMS program."  
 22 Do you see that?  
 23 A. I do see that.  
 24 Q. You say the root cause of

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1 the problem. What problem are you  
 2 referring to there?  
 3 A. The root cause of the  
 4 problem that I'm referring to is the fact  
 5 that -- at issue was the fact that,  
 6 supposedly, the system was generating too  
 7 many flagged orders.  
 8 Q. Is it fair to say, sir, that  
 9 the -- the system was generating too many  
 10 false positives?  
 11 MR. BOGLE: Object to form.  
 12 THE WITNESS: Actually I  
 13 don't think that's fair to say  
 14 without having those orders  
 15 investigated and sufficient due  
 16 diligence behind them. I don't  
 17 know whether -- I'm not sure we  
 18 can say whether it's a false  
 19 positive or a reality. I think  
 20 that's, in large part, a problem,  
 21 the problem.  
 22 BY MR. HYNES:  
 23 Q. Didn't CVS take a look at a  
 24 lot of the orders that were flagging and

<p style="text-align: right;">Page 745</p> <p>1 determine that many of them were false          2 positives?          3 MR. BOGLE: Object to form.          4 THE WITNESS: You want to          5 define what you mean by taking a          6 look, because that's a fairly          7 broad term.          8 BY MR. HYNES:          9 Q. Investigated?          10 Did you review documents or          11 testimony indicating that CVS          12 investigated orders that were flagging on          13 the system and found that many were false          14 positives?          15 MR. BOGLE: Object to form.          16 THE WITNESS: I reviewed          17 testimony that suggested that it          18 was an opinion of at least one CVS          19 employee that there were false          20 positives. But I did not see          21 documentation to support the fact          22 that there was an actual          23 investigation undertaken of those          24 orders to determine whether they</p>	<p style="text-align: right;">Page 747</p> <p>1 his -- that's actually from a document,          2 sir. Did you review his testimony on          3 this issue?          4 A. I did as well.          5 Q. Okay. And did you -- did          6 you review his testimony where he said he          7 found that lower volume stores were          8 flagging very easily?          9 A. Counsel, I recall reviewing          10 all of Mr. Mortelitti's deposition. But          11 I don't recall where in there, in his          12 deposition, statement you're referring          13 to. Again, if you want to show me          14 something, I'll be happy to look at it.          15 Q. Do you recall reviewing his          16 testimony about the back and forth he had          17 with the Buzzeo company about orders that          18 flagged below .65?          19 MR. BOGLE: Object to form.          20 THE WITNESS: Again, if          21 there's something specific that          22 you want me to look at, I will          23 look at it. I do recall reviewing          24 Mr. Mortelitti's deposition.</p>
<p style="text-align: right;">Page 746</p> <p>1 were positive, a false positive or          2 not.          3 And to my recollection of          4 reviewing an IRR report, I don't          5 think just putting eyeballs on the          6 report you can -- you can generate          7 that information.          8 BY MR. HYNES:          9 Q. And are you referring to          10 Mr. Mortelitti?          11 A. I am.          12 Q. Okay. And you write -- I'm          13 on Page 176 now. The second full          14 paragraph, third line down, you write,          15 "Mr. Mortelitti concluded that he could          16 not find one item worthy of investigation          17 below .65."          18 That's what you state there,          19 correct?          20 A. That is what I --          21 Q. Okay.          22 A. That is from his testimony,          23 yes.          24 Q. Okay. And did you review</p>	<p style="text-align: right;">Page 748</p> <p>1 BY MR. HYNES:          2 Q. But sitting here today you          3 don't recall any testimony that went to          4 that issue?          5 A. I don't recall anything that          6 stands out that I can remember.          7 Q. Okay. Then on Page 176.          8 And it's the last sentence before Section          9 5, "Lost Order Data." You write, "Even          10 after the February 2011 retunement which          11 reset algorithm for flagging orders back          12 to the 0.15 level, CVS appears quickly to          13 have returned to operating at the .65          14 level."          15 Do you see that, sir?          16 A. I do.          17 Q. Did you review          18 Mr. Mortelitti's testimony that even          19 after the retunement, the system          20 continued to flag false positives?          21 MR. BOGLE: Object to form.          22 THE WITNESS: Again, I can          23 tell you what I reviewed and what          24 I remember. I remember reviewing</p>

<p style="text-align: right;">Page 749</p> <p>1 his testimony. I can't remember  2 reviewing -- I can't remember the  3 exact section that you're citing  4 to. Again, if you'd like me to  5 look at something, I would be  6 happy to do so.  7 BY MR. HYNES:  8 Q. And I would love to do that,  9 but I have limited time. If I had a full  10 day with you, believe me, I'd have many  11 documents to show you. But I just don't  12 have the time to do that. So we're going  13 to have to make do without it. I hope  14 you understand that. This is not a  15 typical deposition. Trust me. But we're  16 trying to do the best we can.  17 A. And I --  18 Q. And not -- not taking a week  19 of your time. And I know you're trying  20 your best.  21 A. And I'm trying to do my best  22 for you guys as well. And to be accurate  23 with the amount of work that I've done  24 and the amount of documents that I've</p>	<p style="text-align: right;">Page 751</p> <p>1 MR. BOGLE: Object to form.  2 THE WITNESS: Again, as I've  3 answered your question, to the  4 best of my ability, I don't recall  5 that statement, as one statement  6 out of a several-hundred-page  7 deposition. I don't recall it.  8 BY MR. HYNES:  9 Q. I want to turn to Page 177.  10 This is where you address what I call the  11 active ingredient or lost order -- lost  12 order data issue. Does that ring a bell  13 to you?  14 A. Yes, sir, it does.  15 Q. And there you discuss the  16 fact that for a period of time the IRR  17 captured data by item, by the item number  18 of a product, and not by the active  19 ingredient of a product; is that right?  20 A. It's not by active  21 ingredient. But I also thought that it  22 was not only captured by item number, but  23 captured by item name, based on -- based  24 on what Mr. Mortelitti was writing at the</p>
<p style="text-align: right;">Page 750</p> <p>1 looked at, those documents are, you know,  2 imperative for me to be absolutely  3 accurate.  4 Q. That's fair. Did you review  5 any testimony from Mr. Mortelitti that he  6 discussed this issue raising the score  7 after the retunement? Did he discuss  8 that issue with the Buzzeo company?  9 A. I don't recall seeing that.  10 I don't recall.  11 Q. So you don't recall seeing  12 his testimony that the Buzzeo company  13 approved returning to .65?  14 A. I don't recall seeing that  15 at all, nor do I recall seeing any  16 documents of Buzzeo ever -- in all the  17 work that I did on this case, do I recall  18 any documents from Buzzeo saying they  19 approved the .65 to the best of my  20 recollection.  21 Q. Okay. So you didn't read  22 Mr. Mortelitti's testimony where he said  23 they assured us this was going to be  24 acceptable?</p>	<p style="text-align: right;">Page 752</p> <p>1 time.  2 Q. That's fair. And this meant  3 that if the name of an item changed, then  4 its order history would not be  5 incorporated into the IRR going forward  6 with the new name of the item. Is that a  7 fair summary?  8 A. I think -- I think it was  9 more the data was not available to the  10 system for the algorithm. The process  11 was the problem, that that data would be  12 lost.  13 Q. And then also not reflected  14 on the IRR?  15 A. Well, I don't know what you  16 mean by reflected on the IRR.  17 The IRR reflects orders that  18 would in fact -- have been determined by  19 the algorithm to be above a certain  20 score. And then -- a/k/a flagged orders,  21 and they would have been put on the IRR.  22 So I'm not sure I completely understand  23 your question.  24 Q. Okay. Sir, did you make any</p>



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1 attempt to identify which HCPs were  
2 affected by this issue?  
3 MR. BOGLE: Object to form.  
4 BY MR. HYNES:  
5 Q. Let me rephrase it. I'll  
6 try again. Which HCPs -- which HCPs had  
7 a name change or an item -- an item name  
8 change during this period that caused  
9 data for those HCPs to be lost? Did you  
10 make any attempt to figure out which HCPs  
11 had that issue?  
12 MR. BOGLE: Object to form.  
13 THE WITNESS: No, I didn't.  
14 BY MR. HYNES:  
15 Q. Did you attempt to determine  
16 how many HCP orders shipped to Cuyahoga  
17 and Summit County by CVS were affected by  
18 this issue?  
19 A. No. Again my review was of  
20 the process and how it was implemented.  
21 And the fact that you -- your system, or  
22 the algorithm was losing data that it  
23 needed that's essential to do its work  
24 properly, and that was taking time to

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1 fix, that was the issue and why that was  
2 being raised here, that was a problem  
3 that the data was disappearing.  
4 Q. But you didn't -- you didn't  
5 examine this issue at the transactional  
6 level, yes or no?  
7 MR. BOGLE: Object to form.  
8 THE WITNESS: Again, that  
9 wasn't the purpose of the review.  
10 BY MR. HYNES:  
11 Q. Okay. You note on Page 177  
12 that Mr. Mortelitti tried to manually  
13 retrieve historical data from prior  
14 orders.  
15 A. That's what he claimed, yes.  
16 Q. That's what he claimed. Do  
17 you not believe him?  
18 A. That's not what I'm saying.  
19 I'm saying that's what he's claimed. All  
20 I can go by are the four corners of the  
21 record that I reviewed. I'm not making a  
22 judgment one way or the other. I'm  
23 saying that's what the document stated.  
24 Q. Okay. So did you credit his

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1 testimony that he went in -- let me use  
2 your exact words -- and retrieved  
3 historical data that was lost after the  
4 name of an item changed?  
5 MR. BOGLE: Object to form.  
6 BY MR. HYNES:  
7 Q. Did you credit that  
8 testimony?  
9 A. I'm not sure what you mean  
10 by credit. So perhaps --  
11 Q. Did you accept it as true?  
12 MR. BOGLE: Object to form.  
13 THE WITNESS: I accepted it  
14 as it was stated on the record and  
15 saw nothing to the contrary to  
16 cause me to believe otherwise.  
17 BY MR. HYNES:  
18 Q. Okay. So when he -- he  
19 testified that I had to go back to all  
20 previous reports and manually fill in all  
21 the data to do the IRRs, you didn't see  
22 any evidence to contradict that  
23 testimony?  
24 A. In the same fashion, nor did

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1 I see any evidence to support that  
2 contention as well. I saw nothing.  
3 Q. Well, isn't his testimony  
4 evidence, sir?  
5 MR. BOGLE: Object to form.  
6 THE WITNESS: I didn't see  
7 any other documentary evidence to  
8 show -- to demonstrate that he  
9 actually accomplished what he said  
10 he was doing.  
11 BY MR. HYNES:  
12 Q. Okay. Did you consider the  
13 impact that this issue had on the running  
14 of the algorithm itself?  
15 MR. BOGLE: Object to form.  
16 Vague and ambiguous.  
17 THE WITNESS: Can you be  
18 more precise? What do you mean?  
19 BY MR. HYNES:  
20 Q. Did you consider the impact  
21 that the lost order data for a particular  
22 item had on the running of the algorithm?  
23 MR. BOGLE: Same objection.  
24 THE WITNESS: I'm still not

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1 quite sure what you're asking me,  
2 so...  
3 BY MR. HYNES:  
4 Q. Did you review any testimony  
5 indicating that lost order data for a  
6 particular item actually caused more  
7 orders to flag on the IRR?  
8 A. Again, what I reviewed in --  
9 with regard to this would be in my  
10 report, so I would have to go back to  
11 refer to my report.  
12 Q. Well, you said you reviewed  
13 all of Mr. Mortelitti's testimony.  
14 A. I said I read all of his  
15 deposition, is what I said.  
16 Q. Okay. And he testified that  
17 lost order data for a particular item  
18 caused more orders of that item to flag  
19 on the IRR because if there was lost  
20 order data, the IRR would consider there  
21 to be zero orders --  
22 A. Right.  
23 Q. -- in that month.  
24 And, therefore, the average

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1 for that store's ordering of that product  
2 would go down. Did you review that  
3 testimony?  
4 A. I recall that testimony,  
5 yes.  
6 Q. Do you have any reason to  
7 think it's not accurate?  
8 A. Again, I'm not making a  
9 judgment as -- as to accuracy or not. I  
10 look at what is available to review.  
11 That's it.  
12 Q. And did you consider that  
13 testimony in giving your opinions about  
14 the lost order data?  
15 A. I'm sure I did. But again  
16 it goes back to the same statement as  
17 before. The issue here is the algorithm  
18 system, because it's missing data, isn't  
19 functioning the way it was intended to  
20 function.  
21 That's the problem. And it  
22 wasn't fixed. That's the problem.  
23 Q. Well, it was eventually  
24 fixed, wasn't it?

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1 A. Eventually.  
2 Q. Yeah. And if it caused --  
3 it -- the point I'm trying to make is it  
4 caused more orders to flag, and,  
5 therefore, more orders to be reviewed.  
6 So where is the negative outcome on that?  
7 MR. BOGLE: Object to form.  
8 THE WITNESS: It might have.  
9 We don't know. I don't know. I  
10 didn't see any data that said  
11 either -- any -- other than his  
12 testimony, I didn't see anything  
13 either way that indicated that  
14 that's the right outcome. So I  
15 don't know. I can't opine on  
16 that.  
17 What I can say is, if you're  
18 relying on a system that you know  
19 has got a flaw and it's  
20 producing -- it's not working the  
21 way you intended, that is an  
22 issue.  
23 BY MR. HYNES:  
24 Q. Sir, the IRR was first

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1 reviewed at the Lumberton distribution  
2 center, right?  
3 A. That's my recollection.  
4 Q. By Mr. Mortelitti?  
5 A. That is also my  
6 recollection.  
7 Q. And you write he had no  
8 prior experience with suspicious order  
9 monitoring.  
10 A. I can go back and look at  
11 the report, but yes, I recall that.  
12 Q. Okay. But you also don't  
13 have any prior experience with suspicious  
14 order monitoring, do you?  
15 MR. BOGLE: Object to form.  
16 Misstates testimony.  
17 THE WITNESS: I'm not sure I  
18 understand what you mean. I do  
19 have experience working in  
20 regulated -- I did -- I have  
21 reviewed the requirements around  
22 being a suspicious order  
23 monitoring. If you asked if I  
24 built and designed a system, no, I

<p style="text-align: right;">Page 761</p> <p>1 haven't. But that's already on 2 the record. 3 BY MR. HYNES: 4 Q. You've never operated an SOM 5 system either, have you? 6 MR. BOGLE: Object to form. 7 THE WITNESS: No. My role 8 is -- no, I have not. 9 BY MR. HYNES: 10 Q. You've never audited an SOM 11 system, have you? 12 MR. BOGLE: Object to form. 13 THE WITNESS: No, I have not 14 audited an SOM system. But I 15 have -- I have audited PDMA 16 systems which are substantially 17 similar. 18 BY MR. HYNES: 19 Q. But not an SOM system? 20 A. Not an SOM system. 21 Q. And you write that "CVS had 22 one person doing the daily review of the 23 IRR." 24 But there were people in the</p>	<p style="text-align: right;">Page 763</p> <p>1 Mr. Mortelitti's testimony that he sent 2 every HCP order that flagged on the IRR 3 to the field for investigation, right? 4 A. I know that's what he 5 stated, yes. 6 Q. But you don't believe him? 7 MR. BOGLE: Object to form. 8 THE WITNESS: It's not a 9 question of belief. It's a 10 question of I did not see any 11 documentation to support the claim 12 that he was making. 13 It's not a question of 14 belief. It's just I didn't see 15 anything on the record one way or 16 the other. 17 BY MR. HYNES: 18 Q. Do you find Mr. Mortelitti 19 to be credible? 20 MR. BOGLE: Object to form. 21 THE WITNESS: I'm not making 22 a judgment on Mr. Mortelitti's 23 credibility or -- one way or the 24 other. I'm simply looking at what</p>
<p style="text-align: right;">Page 762</p> <p>1 field who investigated orders that were 2 referred by Mr. Mortelitti, weren't 3 there? 4 A. Again, I didn't see evidence 5 of those orders being investigated in the 6 field. 7 Q. You didn't see evidence of 8 those orders being investigated in the 9 field? 10 A. I did not see the people 11 that he's referring to in his testimony, 12 the field analyst. 13 Q. Are you aware that -- that 14 the plaintiffs did not take the 15 deposition of any of those people? 16 MR. BOGLE: Object to form. 17 BY MR. HYNES: 18 Q. Are you aware that -- that 19 the plaintiffs chose not to take the 20 deposition of any of those people? 21 MR. BOGLE: Object to form. 22 THE WITNESS: No, I'm not. 23 BY MR. HYNES: 24 Q. And -- and you note</p>	<p style="text-align: right;">Page 764</p> <p>1 he's saying and saying can I find 2 evidence one way or the other to 3 support it. 4 In a typical way that you do 5 an audit. The -- the audit says 6 we're doing some -- we're doing X 7 and you go to look for support 8 behind that to see whether X is 9 actually happening or not. 10 What I'm saying is I saw an 11 absence on the record. 12 BY MR. HYNES: 13 Q. You point out that Terrence 14 Duggar, the loss prevention manager at 15 the Indianapolis DC, testified that he 16 never monitored any controlled 17 substances. 18 A. Is there a section of the 19 report? 20 Q. Page 174. Do you see that? 21 A. I do see that. 22 Q. Okay. Mr. Mortelitti 23 testified that he sent orders to field 24 viper analysts and regional loss</p>

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<p>1 prevention managers.</p> <p>2 A. That is what I recount from</p> <p>3 his testimony.</p> <p>4 Q. And Mr. Duggar did not hold</p> <p>5 either of those positions, did he?</p> <p>6 A. Don't -- according to what I</p> <p>7 have, I see him as a loss prevention</p> <p>8 manager.</p> <p>9 Q. And not a regional loss</p> <p>10 prevention manager?</p> <p>11 MR. BOGLE: Object to form.</p> <p>12 THE WITNESS: Again, I don't</p> <p>13 know all the positions of</p> <p>14 Mr. Duggar.</p> <p>15 BY MR. HYNES:</p> <p>16 Q. Do you know -- do you know</p> <p>17 the difference between those two</p> <p>18 positions?</p> <p>19 A. Yes, I do know the</p> <p>20 difference between the two positions.</p> <p>21 Q. Okay. So we can agree that</p> <p>22 Mr. Duggar did not hold the position of</p> <p>23 either field viper analyst or regional</p> <p>24 loss prevention manager? According to</p>	<p>1 Do you see that?</p> <p>2 A. I do see that.</p> <p>3 Q. So is it your recollection</p> <p>4 that the program shifted to Knoxville in</p> <p>5 March of 2011?</p> <p>6 A. That is my recollection.</p> <p>7 Q. Okay. You cite Pamela</p> <p>8 Hinkle's testimony for your point on Page</p> <p>9 178 that the process shifted to Knoxville</p> <p>10 in March 2011.</p> <p>11 Do you see that?</p> <p>12 A. I do.</p> <p>13 Q. Okay. I don't have enough</p> <p>14 time to go back and look at her</p> <p>15 testimony, but do you recall that she</p> <p>16 said it was approximately March 2011?</p> <p>17 A. I think we would need to go</p> <p>18 back and look at her testimony to be sure</p> <p>19 what was said, because I can't.</p> <p>20 Q. Did you review</p> <p>21 Mr. Mortelitti's testimony on the subject</p> <p>22 of when the process shifted to Knoxville?</p> <p>23 A. Again, I believe I did. But</p> <p>24 again, is there a particular record --</p>
Page 766	Page 768
<p>1 your report.</p> <p>2 A. According to my report.</p> <p>3 Q. And then you also note on</p> <p>4 Page 175 that -- the IRR recap reports,</p> <p>5 you are familiar with those, sir?</p> <p>6 A. I am familiar with those.</p> <p>7 Q. That the IRR recap reports</p> <p>8 for January 2011 through June 2012 show</p> <p>9 that Mr. Mortelitti deemed very few</p> <p>10 hydrocodone orders needing additional</p> <p>11 investigation.</p> <p>12 Do you see that?</p> <p>13 A. I do.</p> <p>14 Q. And so you're looking at the</p> <p>15 recap reports for January 2011 through</p> <p>16 June 2012. But then on Page 178 -- let's</p> <p>17 just flip ahead real quick.</p> <p>18 A. 178.</p> <p>19 Q. First sentence under Number</p> <p>20 1, "IRR Review, Ship to Knoxville." You</p> <p>21 write, "By March 2011... responsibility</p> <p>22 shifted from Mr. Mortelitti at the</p> <p>23 Lumberton DC to Ms. Hinkle's team in the</p> <p>24 Knoxville DC."</p>	<p>1 particular document that you'd like to</p> <p>2 cite to, Counselor? Because we're</p> <p>3 looking at a bunch of different</p> <p>4 documents.</p> <p>5 Q. Okay. I'm just going to</p> <p>6 tell you what he said, and I'll ask you</p> <p>7 if you recall it sitting here right now.</p> <p>8 He said, "I'm not 100 percent sure of the</p> <p>9 month, when they hired an analyst for</p> <p>10 Knoxville. I believe his name was Cain,</p> <p>11 C-A-I-N. That's when the process went</p> <p>12 there."</p> <p>13 Do you recall reviewing that</p> <p>14 testimony?</p> <p>15 MR. BOGLE: Object to form.</p> <p>16 THE WITNESS: I can't recall</p> <p>17 that specific testimony, no.</p> <p>18 BY MR. HYNES:</p> <p>19 Q. Do you know who Thomas Cain</p> <p>20 is?</p> <p>21 A. Again, I don't recall the</p> <p>22 name.</p> <p>23 Q. I'm going to show you a</p> <p>24 document.</p>

<p style="text-align: right;">Page 769</p> <p>1 A. Okay. 2 (Document marked for 3 identification as Exhibit 4 Whitelaw-18.) 5 BY MR. HYNES: 6 Q. We'll mark this as Whitelaw 7 Exhibit 18. Take a look at that 8 document, sir. 9 A. Sure. 10 Q. You got it? 11 MR. HYNES: Brandon. I have 12 one copy for you guys. I'm sure 13 Dan has memorized the document. 14 BY MR. HYNES: 15 Q. Sir, I want to draw your 16 attention to the e-mail that's the second 17 one down on the page. And that's from 18 Steven Cain, correct? 19 A. That's what it says. 20 Q. It's dated January 18, 2011? 21 A. That's also what it says. 22 Q. And going to the bottom, it 23 gives his title under his signature block 24 as loss prevention analyst, Knoxville DC?</p>	<p style="text-align: right;">Page 771</p> <p>1 A. Let's look at my reliance 2 list and double-check. 3 Q. It's not on there. 4 A. Then I did not -- 5 MR. BOGLE: If you want to 6 check, you can check. 7 THE WITNESS: All right. 8 I'm going to check. 9 BY MR. HYNES: 10 Q. Is it -- is it your 11 testimony that you only reviewed the 12 documents on your reliance list? 13 MR. BOGLE: Object to form. 14 THE WITNESS: Could you be 15 more specific? 16 BY MR. HYNES: 17 Q. Throughout your work on this 18 engagement, did you review any documents 19 that are not on your reliance list? 20 A. Throughout the work I 21 used -- what's on my reliance lists what 22 I used to formulate my opinions in this 23 report. 24 Q. I'm asking a different</p>
<p style="text-align: right;">Page 770</p> <p>1 A. That's what it does also 2 say. 3 Q. Okay. And the subject of 4 the e-mail is "Control IRR Dated 5 1/18/11," right? Correct? 6 A. Yes. 7 Q. And he writes, "Today's 8 control IRR report contained four 9 suspicious orders from the following DCs: 10 Tennessee, La Habra, Orlando, and Indy;" 11 correct? 12 A. Yes, it does say that. 13 Q. So does this document 14 refresh your recollection that the 15 process had moved to Knoxville by January 16 of 2011? 17 MR. BOGLE: Object to form. 18 THE WITNESS: Again, I see 19 the document in front of me. All 20 I can comment is what the document 21 says. 22 BY MR. HYNES: 23 Q. Do you recall ever -- have 24 you reviewed this document before today?</p>	<p style="text-align: right;">Page 772</p> <p>1 question, not the documents you used to 2 formulate your opinions. I'm asking what 3 documents you reviewed. To the best of 4 your recollection, sitting here today, 5 did you ever review any documents 6 produced by any party in this case that 7 are not listed in your reliance list? 8 A. To the best of my 9 recollection, the reliance list is as 10 full and complete a review record as I 11 can remember. 12 Q. Did you say full and 13 complete review record? 14 A. Of what I looked at. 15 Q. Okay. Thank you. 16 MR. BOGLE: Just so we're 17 clear, do you want him to look 18 whether it's on there, or do you 19 want him to rely just whether it 20 is or isn't? 21 MR. HYNES: It's not on 22 there. But he can check. 23 MR. BOGLE: I just want to 24 make sure we're clear on what he's</p>



<p style="text-align: right;">Page 773</p> <p>1 asked to do.</p> <p>2 MR. HYNES: Okay.</p> <p>3 BY MR. HYNES:</p> <p>4 Q. Let's move on.</p> <p>5 MR. HYNES: I don't -- he</p> <p>6 doesn't recognize the name Thomas</p> <p>7 Cain. It's not -- it's not on</p> <p>8 there.</p> <p>9 MR. BOGLE: Okay. That's</p> <p>10 fine.</p> <p>11 BY MR. HYNES:</p> <p>12 Q. Sir, on Page 178, you write</p> <p>13 that after the process went to Pam</p> <p>14 Hinkle's team in the Knoxville DC, that</p> <p>15 initially Shannon Miller was tasked with</p> <p>16 the daily IRR reviews.</p> <p>17 Do you see that?</p> <p>18 A. I do see that.</p> <p>19 Q. Okay. There's no mention of</p> <p>20 Thomas Cain, is there?</p> <p>21 MR. BOGLE: Object to form.</p> <p>22 BY MR. HYNES:</p> <p>23 Q. Sorry. Steven Cain?</p> <p>24 A. No, there was no mention of</p>	<p style="text-align: right;">Page 775</p> <p>1 your report the IRR recaps -- IRR recap</p> <p>2 reports, don't you?</p> <p>3 A. I do.</p> <p>4 Q. And don't those reflect</p> <p>5 orders being -- I think one of them you</p> <p>6 cited was one that we just discussed from</p> <p>7 January 2011 to some point in 2012.</p> <p>8 Don't those show orders</p> <p>9 being referred to field viper analysts</p> <p>10 for further investigation?</p> <p>11 MR. BOGLE: Object to form.</p> <p>12 THE WITNESS: They list</p> <p>13 orders that need further</p> <p>14 investigation. Whether they're</p> <p>15 actually forwarded to the field or</p> <p>16 not and whether there's an</p> <p>17 investigation record for each of</p> <p>18 those files, to my recollection, I</p> <p>19 don't recall seeing those in the</p> <p>20 IRR recap report.</p> <p>21 BY MR. HYNES:</p> <p>22 Q. Do you recall seeing a field</p> <p>23 or a column that was entitled "Field LP</p> <p>24 Contacted"?</p>
<p style="text-align: right;">Page 774</p> <p>1 her -- of him. I'm sorry.</p> <p>2 Q. And they continued -- the</p> <p>3 analysts in Knoxville continued the</p> <p>4 practice of reviewing -- of referring</p> <p>5 flagged orders to the field for</p> <p>6 investigation, correct?</p> <p>7 MR. BOGLE: Object to form.</p> <p>8 THE WITNESS: I'm not sure I</p> <p>9 understand your question.</p> <p>10 BY MR. HYNES:</p> <p>11 Q. When I say the field, I'm</p> <p>12 talking about the field viper analyst.</p> <p>13 They continued the practice of referring</p> <p>14 orders to the field viper analysts for</p> <p>15 investigation?</p> <p>16 MR. BOGLE: Object to form.</p> <p>17 THE WITNESS: All I can</p> <p>18 comment on is one e-mail that</p> <p>19 you've shown me which says that</p> <p>20 they took those four suspicious</p> <p>21 orders and forwarded them to the</p> <p>22 field.</p> <p>23 BY MR. HYNES:</p> <p>24 Q. Okay. Well, you cite in</p>	<p style="text-align: right;">Page 776</p> <p>1 A. Do you have something for me</p> <p>2 to look at, Counselor? Because again, I</p> <p>3 looked at a lot of documents.</p> <p>4 Q. Sitting here today, do you</p> <p>5 recall seeing a column entitled "Field LP</p> <p>6 Contacted"?</p> <p>7 A. Again, I don't recall --</p> <p>8 recall it. I do recall Mr. Mortelitti's</p> <p>9 testimony to the effect that, I picked up</p> <p>10 the phone and called people. But I</p> <p>11 don't -- again, I -- my issue was I</p> <p>12 didn't see any documentation. I didn't</p> <p>13 see paperwork other than maybe a</p> <p>14 reference to a phone call.</p> <p>15 I didn't see a due diligence</p> <p>16 file. That's -- that is my beef and</p> <p>17 that's been my issue all along.</p> <p>18 MR. HYNES: I move to</p> <p>19 strike -- to strike everything</p> <p>20 after "again I don't recall" --</p> <p>21 "recall it."</p> <p>22 BY MR. HYNES:</p> <p>23 Q. Turning to Page 179. You</p> <p>24 say, "Ultimately Ms. Hinkle gained two</p>

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1 loss prevention analysts assigned to the  
2 SOM program."  
3 Who are -- who are the two  
4 loss prevention analysts you're referring  
5 to?  
6 A. I'd have to go back and  
7 look -- and look at her testimony and go  
8 back to -- refer to the report and read  
9 it. Do you want to take the time?  
10 Q. The names aren't in your  
11 report.  
12 A. Then I'd have to go back and  
13 reconstruct it. I don't rightly know the  
14 names off the top of my head.  
15 Q. Okay. And are you aware  
16 that at some point in mid 2012, the IRR  
17 process shifted to the Indianapolis DC?  
18 A. I am -- I do have  
19 recollection of that.  
20 Q. You do?  
21 A. I do.  
22 Q. Okay. And can you tell me,  
23 when the program was in Indianapolis, who  
24 worked on it?

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1 A. I don't recall at this  
2 point.  
3 Q. You don't recall. Are you  
4 aware of any -- did you see any evidence  
5 indicating that when the program was in  
6 Knox -- excuse me, was in Indianapolis,  
7 that any outside -- outside consultants  
8 who were former DEA agents assisted with  
9 the process?  
10 A. Is there a specific document  
11 or a specific section you're referring  
12 to, counsel? Because at this point I'm  
13 not sure what you're asking.  
14 Q. I'm just asking sitting here  
15 today, do you recall reviewing any  
16 evidence, any documents, or any testimony  
17 indicating that outside consultants who  
18 were former DEA agents assisted with the  
19 operation of the SOM program when it was  
20 in Indianapolis.  
21 MR. BOGLE: Object to form.  
22 BY MR. HYNES:  
23 Q. It's a yes or no question.  
24 A. I don't have any

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1 recollection of any -- of seeing those  
2 documents, but again, if there's  
3 something you would like me to review,  
4 I'd be happy to review it.  
5 MR. BOGLE: When you reach a  
6 good stopping point, I was going  
7 to break for lunch.  
8 MR. HYNES: Let's go off the  
9 record for a moment.  
10 THE VIDEOGRAPHER: Going off  
11 the record, 12:45 p.m.  
12 - - -  
13 (Lunch break.)  
14 - - -  
15 AFTERNOON SESSION  
16 - - -  
17 THE VIDEOGRAPHER: We are  
18 back on the record at 1:34 p.m.  
19 - - -  
20 EXAMINATION (Cont'd.)  
21 - - -  
22 BY MR. HYNES:  
23 Q. Welcome back, Dr. Whitelaw.  
24 A. Thank you, sir.

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1 Q. I'm going to turn your  
2 attention to Page 168 of your report.  
3 A. 168 you said, yes?  
4 Q. Yes, that's correct.  
5 A. Okay. I'm here.  
6 Q. Okay. And on that page you  
7 discuss the DEA's speaking points,  
8 correct?  
9 A. I do.  
10 Q. Yeah. And the last sentence  
11 on that page you write, "The DEA speaking  
12 points misrepresented the CVS program  
13 when it was created and approved to be  
14 given to the DEA."  
15 And when you say when it was  
16 created and approved, I think you're  
17 referring to the speaking points; is that  
18 correct?  
19 A. I am referring to that  
20 particular deck, yes, I am.  
21 Q. Sir, you dispute that when  
22 those speaking points were created, and I  
23 believe it's August of 2010, that CVS did  
24 not intend to shift the IRR review

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1 process to each distribution center?  
2 MR. BOGLE: Object to form.  
3 THE WITNESS: Can you ask me  
4 the question again, please?  
5 BY MR. HYNES:  
6 Q. Do you dispute the fact that  
7 when those speaking points were  
8 created -- that was a bad question. I'm  
9 sorry. I'll do this better.  
10 Do you dispute the fact that  
11 when those speaking points were created,  
12 CVS intended to shift the IRR review  
13 process to each distribution center?  
14 A. I have no way of knowing  
15 what CVS intended. What I do know is on  
16 the record, that is that it does not  
17 reflect what they were currently doing.  
18 Q. If you go up three  
19 sentences, in that paragraph, maybe four,  
20 you note that "the DEA SOP manual issued  
21 two days before the date of this DEA's  
22 speaking points stated that during the  
23 month of September 2010, the report will  
24 be transitioned to each pharmacy DC."

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1 Does that refresh your  
2 recollection as to whether CVS intended  
3 at the time the speaking points were  
4 drafted to transition the review of the  
5 IRR to each distribution center?  
6 A. It refreshes my recollection  
7 based on the document we just looked at.  
8 There was a plan to transition and it  
9 never came to fruition.  
10 Again, the point that I have  
11 is that they -- as far as I've seen, I  
12 have never saw an updated speaking points  
13 deck showing that they actually corrected  
14 the record. That was my issue.  
15 Q. You never saw an updated  
16 speaking points deck?  
17 A. I don't recall seeing an  
18 updated speaking points deck.  
19 Q. Sitting here today you are  
20 not aware that CVS ever revised the DEA  
21 speaking points?  
22 A. To the best of my  
23 recollection, I don't remember it, no.  
24 Q. Did you ask counsel for any

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1 documents related to a revised version of  
2 the DEA speaking points?  
3 A. I asked counsel for a lot of  
4 things. I can't remember every document  
5 request that I made from counsel.  
6 Q. Well, in preparing this  
7 section of your report, you never  
8 inquired of counsel whether the DEA  
9 speaking points had ever been revised?  
10 A. Again, I don't recall  
11 specifically asking that question, but I  
12 would have asked to crosscheck that  
13 information, and was there any additional  
14 decks.  
15 Q. Okay.  
16 A. I would have asked for  
17 additional documents.  
18 Q. Okay. The version that  
19 you're talking about, the August 2010  
20 version, sitting here, do you recall any  
21 evidence indicating that those speaking  
22 points were used with the DEA?  
23 A. Again, I need to see the  
24 document to refresh my recollection. I

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1 looked at a lot of things.  
2 Q. I don't have a document. Do  
3 you have --  
4 A. I don't have the document  
5 either so I can't help you there.  
6 Q. So you don't recall seeing  
7 any document where for example, John  
8 Mortelitti used it with the DEA?  
9 MR. BOGLE: Object to form.  
10 THE WITNESS: I don't recall  
11 seeing any -- any document the way  
12 you're describing. I did see  
13 documents that was intended to be  
14 used with DEA, but I don't  
15 remember anything further than  
16 that.  
17 BY MR. HYNES:  
18 Q. So you don't recall seeing a  
19 document where John Mortelitti explained  
20 that the talking points, that some  
21 aspects of them were out of date?  
22 MR. BOGLE: Object to form.  
23 THE WITNESS: Again, if it's  
24 not in the record, if it's not in

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1 my report, I don't recall --  
2 BY MR. HYNES:  
3 Q. Okay.  
4 A. -- seeing a document that  
5 fits your exact description.  
6 Q. You are aware, aren't you,  
7 that CVS produced some of its DEA SOPs to  
8 the DEA during DEA inspections? Have you  
9 seen documents indicating that?  
10 A. Again, I looked at a lot of  
11 documents, Paul. I don't -- can't --  
12 unless you can point me to a specific  
13 document and help me here, I don't have a  
14 recollection of it.  
15 Q. All right. So sitting here  
16 today, you are not aware that CVS ever  
17 produced the DEA SOP --  
18 A. I --  
19 MR. BOGLE: Wait until he  
20 finishes.  
21 BY MR. HYNES:  
22 Q. -- to DEA.  
23 MR. HYNES: Thanks.  
24 MR. BOGLE: Object to form.

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1 You can answer.  
2 THE WITNESS: Again, I  
3 don't.  
4 BY MR. HYNES:  
5 Q. Have you reviewed any  
6 versions of the DEA SOP?  
7 A. Yes. And they're listed in  
8 my report.  
9 Q. And would you agree that  
10 those SOPs reflect that the IRR review  
11 was done in a central location?  
12 A. I would have to go back and  
13 review each and every version that I  
14 looked at to be sure of that. So --  
15 Q. Do you have any reason to  
16 believe they don't state that?  
17 MR. BOGLE: Object to form.  
18 THE WITNESS: I have no  
19 opinion -- without seeing the  
20 documents themselves, I have no  
21 opinion whatsoever at the moment.  
22 BY MR. HYNES:  
23 Q. I want to turn your  
24 attention to Page 170 of your report.

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1 A. I'm there.  
2 Q. Last paragraph, first  
3 sentence, you state that -- and this  
4 relates to the PDMM reports. Do you  
5 remember those?  
6 A. I do remember those.  
7 Q. You state that, "The  
8 reports" -- this is the first sentence of  
9 the last paragraph -- "were deficient as  
10 an SOM report."  
11 Do you see that? Do you see  
12 that, sir?  
13 A. I do see that.  
14 Q. Okay. And then going up  
15 above the block quoted language, you say  
16 CVS represented that PDMM reports were  
17 part of the company's efforts to monitor  
18 suspicious orders.  
19 Do you see that?  
20 A. I do see that.  
21 Q. Can you tell me where CVS  
22 said that?  
23 A. I can't point to a specific  
24 quote right at this moment. No.

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1 Q. Let's look at the block  
2 moment. And there you're quoting the  
3 deposition testimony of Mark Vernazza.  
4 Do you know who Mark Vernazza is?  
5 A. Yes, I do know who Mark  
6 Vernazza is.  
7 Q. And who is he?  
8 A. As I recall, he was counsel  
9 for CVS. He was also the 30(b)(6)  
10 witness.  
11 Q. That's right. That's right.  
12 So he was giving CVS's testimony, would  
13 you agree with that, as a corporate  
14 witness?  
15 A. Yes.  
16 Q. The testimony that you cite,  
17 "This report was not what we deemed a  
18 suspicious order monitoring report. It's  
19 relevant to orders and order size and,  
20 some degree, order pattern. But the  
21 point of this was not to produce results  
22 for the purposes of determining whether  
23 suspicious orders were made and reporting  
24 those to the DEA."

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1 Did I read that correctly?

2 A. You did read that correctly.

3 Q. So would you interpret that

4 testimony of Mr. Vernazza to be that the

5 PDMR reports were not SOM reports?

6 A. That would be -- I'm sorry.

7 Can you ask the question again, please.

8 Q. Do you agree that that

9 testimony states that the PDMR reports

10 were not SOM reports?

11 A. I would say that's what he

12 said, yes.

13 Q. Do you have any other reason

14 to believe that the PDMR reports were SOM

15 reports?

16 A. Actually, at the moment, I

17 don't have a document that I can point

18 to.

19 Q. Okay. We've talked a lot

20 about the IRR, right?

21 A. We have talked a lot about

22 the IRR.

23 Q. And would you agree that

24 that's a SOM report?

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1 A. I would say that the IRR is

2 a report of orders that have flagged to

3 be --

4 Q. Flagged orders as

5 potentially suspicious?

6 MR. BOGLE: Wait until he

7 finishes, Counsel.

8 Are you finished? Finish

9 your answer, and then he'll --

10 MR. HYNES: Sorry about

11 that.

12 THE WITNESS: Can you back

13 up and ask the question again?

14 BY MR. HYNES:

15 Q. Would you agree that the

16 IRRs were the report that CVS used to

17 evaluate whether orders were suspicious,

18 the report that CVS used in its SOM

19 program?

20 A. I would say it was a tool

21 that was used in the SOMs program. Yes.

22 Q. Would you agree that it's a

23 SOM report?

24 A. I think we're splitting

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1 hairs. I would say it's closer to being

2 a SOMs report if it -- based on what I

3 know of the algorithm, but again I'm not

4 a --

5 Q. Closer than --

6 MR. BOGLE: Are you done?

7 THE WITNESS: Because of the

8 complexity of the algorithm and

9 all of the factors that I saw, no,

10 I did not understand the math.

11 But I'm not a mathematician. I'm

12 not sure. So it's pretty

13 complicated. It looked, at least

14 on its face, based on my

15 understanding that it would be

16 closer to a SOMs report in the

17 sense that it was looking at

18 pattern and frequency and sizes,

19 well, from what I can tell.

20 BY MR. HYNES:

21 Q. And --

22 A. And scoring the order, and

23 then above a certain score, those orders

24 were then hitting the IRR as needing

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1 further follow-up in due diligence.

2 Q. When you say closer to a SOM

3 report, you mean closer to the PDMR

4 report? Is that the comparison that

5 you're making?

6 A. I think that's the

7 comparison I'm drawing.

8 Q. Okay. Okay. And the last

9 sentence of that last paragraph, you

10 conclude that the PDMR reports were

11 ineffective anti-diversion control.

12 Do you see that statement?

13 A. I do see that statement.

14 Q. You are aware, aren't you,

15 Dr. Whitelaw, that those reports were one

16 of several tools that CVS used to prevent

17 diversion?

18 MR. BOGLE: Object to form.

19 THE WITNESS: Would you

20 clarify those reports?

21 BY MR. HYNES:

22 Q. The PDMR reports.

23 A. Which reports are you

24 talking about?



<p style="text-align: right;">Page 793</p> <p>1 Q. The PDMR reports, those were  2 one of several reports that CVS used to  3 prevent diversion.  4 MR. BOGLE: Object to form.  5 THE WITNESS: I would  6 testify that that was the only  7 report that I saw that was even an  8 attempt at a suspicious order.  9 I'm not sure what you're referring  10 to. So can you help me here?  11 BY MR. HYNES:  12 Q. I'm just -- I'm just trying  13 to establish that the PDMR reports were  14 one of several reports that CVS used in  15 it's anti-diversion program. For  16 example, the IRR report is a different  17 report than the PDMR report and also was  18 used in an anti-diversion manner.  19 MR. BOGLE: Object to form.  20 BY MR. HYNES:  21 Q. Do you agree with that?  22 A. Yes, I agree.  23 Q. Okay. Sir, the PDMR  24 reports, did you review any of those?</p>	<p style="text-align: right;">Page 795</p> <p>1 are at. I'm not saying it's not  2 on here. I just don't see where  3 you're at.  4 MR. HYNES: I'm going to go  5 to a different part in this.  6 BY MR. HYNES:  7 Q. First paragraph under the  8 PDMR reports. Second to last sentence,  9 "Their reports that show how much was  10 shipped to and dispensed from a  11 pharmacy."  12 Do you see that?  13 A. I see it.  14 Q. Do you recall writing it?  15 A. I do recall writing it.  16 Q. Okay. So does that refresh  17 your recollection that these reports  18 incorporated dispensing data?  19 A. In some form or another they  20 incorporated dispensing data.  21 MR. BOGLE: Object to form.  22 THE VIDEOGRAPHER: If you  23 can just pull your mic down.  24 BY MR. HYNES:</p>
<p style="text-align: right;">Page 794</p> <p>1 A. Honestly, I can't remember  2 at this point.  3 Q. Can you tell me what they  4 looked at?  5 A. Again, I can't remember at  6 this point in time. I'm sorry.  7 Q. Do you know whether --  8 A. Do you have a document that  9 you would like me to look at?  10 Q. I don't. Do you know  11 whether they incorporated dispensing  12 data?  13 A. Again, I'd like to see the  14 report to be absolutely certain. I  15 don't -- I would be speculating.  16 Q. Well, you write on Page 170  17 that the reports compared orders made  18 with distribution centers to dispensing.  19 So does that refresh your recollection  20 that these reports incorporated  21 dispensing data?  22 MR. BOGLE: Can you tell me  23 exactly where you're looking at  24 here? I'm not seeing where you</p>	<p style="text-align: right;">Page 796</p> <p>1 Q. Sir, you state on Page 178,  2 so eight pages up. The first sentence  3 under Number 2, "Use of MicroStrategy."  4 Do you see that?  5 I'll give you some time to  6 get there.  7 A. I do see it.  8 Q. First sentence, second line,  9 you say that "Only tools" -- actually,  10 let me go back to the first line.  11 "Although it is not  12 completely clear, it appears that"... "the  13 only tools available for the due  14 diligence follow-up prior to 2012 were  15 the PDMR (VIPER) reports."  16 Do you see that?  17 A. I do see that.  18 Q. And if you look at  19 Footnote 1018, you quote Mr. Mortelitti's  20 testimony.  21 A. I did.  22 Q. At Pages 67 to 68. But he  23 testified that he didn't know what the  24 field viper analyst had access to. Do</p>

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1 you remember reviewing that testimony?  
2 A. I would need to see his  
3 testimony again. And again it's --  
4 you're asking me specifics about specific  
5 testimony. If you have something to show  
6 me, I will look at it.  
7 Q. Well, my question for you --  
8 A. This is not a memory test,  
9 Paul.  
10 Q. Understood. Understood. I  
11 have limited time.  
12 My question to you is, are  
13 you aware of any other evidence in the  
14 record indicating that the PDMR reports  
15 were the only tools available for due  
16 diligence prior to 2012?  
17 A. And my answer would be I'm  
18 not aware at --  
19 Q. Okay.  
20 A. -- without looking through  
21 the report and his testimony.  
22 Q. Thank you.  
23 Yesterday you testified, and  
24 I had the court reporter pull this for

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1 me, and I can show it to you. This was  
2 during Walgreens questioning.  
3 You said, "Having reviewed  
4 the documents, having asked for the  
5 information, having looked at what they  
6 were using to determine suspicious order  
7 monitoring, based on my review, I did not  
8 see them" -- and "them" you're referring  
9 to CVS and Walgreens -- "using dispensing  
10 data in their own -- to try to clear red  
11 flags for various suspicious orders."  
12 Do you remember giving  
13 testimony yesterday that you did not see  
14 any documents indicating that CVS and  
15 Walgreens had used dispensing data to try  
16 to clear red flags?  
17 MR. BOGLE: Since you've got  
18 it pulled, can you show him the  
19 question and answer?  
20 MR. HYNES: Yeah.  
21 MR. BOGLE: The full  
22 question and answer?  
23 MR. HYNES: I've underlined  
24 it right there.

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1 THE WITNESS: I see it.  
2 MR. HYNES: I'll take that  
3 back. Thanks, Brandon.  
4 BY MR. HYNES:  
5 Q. On Page 178 of your report,  
6 last paragraph, are you there?  
7 A. I'm there.  
8 Q. You write, second sentence,  
9 "Analysts using MicroStrategy had access  
10 to information of patient ID number,  
11 doctors, how the drugs were paid for,  
12 dispensing data, the patient population  
13 that was purchasing the drug, information  
14 on the pharmacy, and information on the  
15 patient."  
16 A. I see it.  
17 Q. Doesn't that indicate that  
18 analysts had access to dispensing data?  
19 A. It does, but I think the  
20 point I was trying to make to the record  
21 that you were going back to was you  
22 weren't using it on a consistent basis.  
23 If we look at the orders  
24 that it was being applied to, you weren't

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1 applying micro strategies to every single  
2 flagged order. You were applying it to a  
3 handful of flagged orders. That was the  
4 overall issue. So it wasn't a consistent  
5 use.  
6 Q. Okay. You --  
7 A. And --  
8 Q. Go ahead.  
9 MR. BOGLE: Go ahead.  
10 THE WITNESS: If I wasn't  
11 clear then, I'm trying to be clear  
12 now.  
13 BY MR. HYNES:  
14 Q. Okay. So your testimony was  
15 you had not seen any documents, any  
16 documents that showed CVS or Walgreens  
17 using dispensing data.  
18 Is it your testimony today  
19 that you have seen documents showing CVS  
20 using dispensing data to clear red flags?  
21 MR. BOGLE: Object to form.  
22 THE WITNESS: I have seen  
23 the availability of the tool. I  
24 have not seen anywhere in the due

<p style="text-align: right;">Page 801</p> <p>1 diligence files presented that you 2 were using prescription data. And 3 I know from the documents I 4 reviewed that you were only 5 looking at a handful of those 6 IRRs. 7 BY MR. HYNES: 8 Q. Did you ask counsel for due 9 diligence documents indicating whether 10 CVS used dispensing data to clear red 11 flags? 12 A. I believe I did. 13 Q. And you didn't receive any? 14 MR. BOGLE: Object to form. 15 THE WITNESS: Again, all 16 the -- all the documents I've 17 reviewed, I can't remember every 18 document I've reviewed. 19 BY MR. HYNES: 20 Q. Okay. 21 (Document marked for 22 identification as Exhibit 23 Whitelaw-19.) 24 BY MR. HYNES:</p>	<p style="text-align: right;">Page 803</p> <p>1 your counsel Mr. Goetz used at the 2 deposition of Aaron Burtner. Do you 3 recall seeing this document? 4 A. I can go to my reliance 5 list, but I don't recall it off the top 6 of my head. 7 Q. Did you review Mr. Burtner's 8 deposition transcript in its entirety? 9 A. Again, I don't recall that I 10 reviewed Mr. Burtner's testimony in its 11 entirety or not. 12 Q. Okay. And then sitting 13 back, when you reviewed a deposition, 14 would you -- transcript, would you also 15 review the exhibits? 16 A. Yes. 17 Q. Sir, this is an e-mail dated 18 February 7, 2014, from Shauna Helfrich. 19 Do you see that on the first 20 page? 21 A. I do. 22 Q. And she notes below two 23 orders -- or one store that flagged for 24 two orders of HCPs.</p>
<p style="text-align: right;">Page 802</p> <p>1 Q. This will be Exhibit 2 Whitelaw 19. 3 MR. HYNES: I put it on the 4 wrong one. 5 BY MR. HYNES: 6 Q. Here you go, Dr. Whitelaw. 7 A. Thanks. 8 MR. HYNES: Did you guys get 9 a copy? 10 MR. BOGLE: Yeah. 11 BY MR. HYNES: 12 Q. Sir, I'll give you a minute 13 to take a look at the document. 14 MR. BOGLE: Do you want him 15 to just let you know when he's 16 done? 17 MR. HYNES: Sure. 18 MR. BOGLE: Will that help 19 you? 20 MR. HYNES: Sure. 21 BY MR. HYNES: 22 Q. Ready, sir? 23 A. I'm ready. 24 Q. Sir, this is a document that</p>	<p style="text-align: right;">Page 804</p> <p>1 Do you see that? 2 A. I do. 3 Q. She states at the end of the 4 e-mail, "Based on the information 5 reviewed, this order has been approved." 6 Do you see that? 7 A. I do see it. 8 Q. And then attached to this 9 e-mail is some data. And I just want to 10 warn you, this has been designated as 11 HIPAA protected, because, if you turn to 12 the last page, it includes patient and 13 dispensing information. 14 Do you see that? 15 A. I do see that. 16 Q. So it has date as a -- as a 17 column, patient age, product, patient ID, 18 and then moving over, the GCN number and 19 the dispensing quantity. 20 Do you see all that? 21 A. I do. 22 Q. Would you agree that this is 23 a due diligence file indicating that 24 dispensing data was used to clear an</p>

<p style="text-align: right;">Page 805</p> <p>1 order that had been flagged on the IRR?</p> <p>2 A. I would agree that it's a</p> <p>3 due diligence file from 2014 showing the</p> <p>4 use of dispensing data.</p> <p>5 (Document marked for</p> <p>6 identification as Exhibit</p> <p>7 Whitelaw-20.)</p> <p>8 BY MR. HYNES:</p> <p>9 Q. We'll mark this as Whitelaw</p> <p>10 20.</p> <p>11 MR. HYNES: That's for him.</p> <p>12 And this one is for you gentlemen.</p> <p>13 BY MR. HYNES:</p> <p>14 Q. Dr. Whitelaw, to save you a</p> <p>15 little bit of time. I just want to ask</p> <p>16 you about the first page and the last</p> <p>17 page.</p> <p>18 A. Let me just go through the</p> <p>19 whole document. But I appreciate you</p> <p>20 trying to save me some time.</p> <p>21 I see it.</p> <p>22 Q. This is a document that</p> <p>23 Mr. Goetz used during the deposition of</p> <p>24 Gary Milikan. Do you recall reviewing</p>	<p style="text-align: right;">Page 807</p> <p>1 A. I see it.</p> <p>2 Q. And then if you turn to the</p> <p>3 last page, there's a table, and I'll be</p> <p>4 the first to admit it's hard to read</p> <p>5 because these were hard copies we had to</p> <p>6 copy.</p> <p>7 But it has a date -- confer</p> <p>8 date, patient age, label name of the</p> <p>9 product, patient ID, GCN number, and</p> <p>10 dispensing quantity, among others.</p> <p>11 Do you see that?</p> <p>12 A. I do.</p> <p>13 Q. Sir, would you also agree</p> <p>14 that this is a due diligence file that</p> <p>15 includes dispensing data?</p> <p>16 A. From 2013, yes.</p> <p>17 Q. Okay. Thank you. Let's</p> <p>18 turn to Page 179.</p> <p>19 The last paragraph, you say,</p> <p>20 "Delivered at the end of 2012, AGI Store</p> <p>21 Metrics was the successor program to the</p> <p>22 MicroStrategy tool."</p> <p>23 Do you see that?</p> <p>24 And do you remember what the</p>
<p style="text-align: right;">Page 806</p> <p>1 this document before today?</p> <p>2 A. I do not recall, but I can</p> <p>3 go and check the reliance list if you</p> <p>4 would like.</p> <p>5 Q. That's not necessary.</p> <p>6 You see the date of the</p> <p>7 document, December 10, 2013, on the first</p> <p>8 page?</p> <p>9 A. I do see that document.</p> <p>10 Q. Okay.</p> <p>11 A. Or I'm sorry -- that date.</p> <p>12 Pardon me.</p> <p>13 Q. You see it's from Shauna</p> <p>14 Helfrich?</p> <p>15 A. I see it's from Shauna</p> <p>16 Helfrich.</p> <p>17 Q. You see that it relates to</p> <p>18 an order of HCPs from Store 4101.</p> <p>19 A. That's what it purports to</p> <p>20 be.</p> <p>21 Q. And the last line of the</p> <p>22 e-mail she writes, "Based on the</p> <p>23 information reviewed, these orders have</p> <p>24 been approved"?</p>	<p style="text-align: right;">Page 808</p> <p>1 Store Metrics were?</p> <p>2 A. Yes, I do remember what the</p> <p>3 Store Metrics were. And I do remember</p> <p>4 writing this sentence. And I do remember</p> <p>5 reading this document.</p> <p>6 Q. Okay. And you write, next</p> <p>7 sentence, "While the Store Metrics</p> <p>8 program provided the same information as</p> <p>9 MicroStrategy, its primary advantage was</p> <p>10 that it put that information into one</p> <p>11 combined dashboard for review."</p> <p>12 Do you see that?</p> <p>13 A. Yes, I do see that.</p> <p>14 Q. Do you recall whether you</p> <p>15 reviewed any Store Metric reports?</p> <p>16 A. Again, I don't recall</p> <p>17 whether I reviewed the actual store</p> <p>18 metrics reports or not. Again, I</p> <p>19 reviewed a lot of documents.</p> <p>20 Q. Did you ask for any of them?</p> <p>21 A. I don't recall a specific</p> <p>22 ask, but I'm sure I did.</p> <p>23 Q. If you -- strike that.</p> <p>24 Going over to Page 180.</p>

<p style="text-align: right;">Page 809</p> <p>1 First full paragraph, you essentially  2 make the point that the data in the Store  3 Metrics report did not update. Is that  4 fair to say?  5 A. That was certainly the  6 record that I saw and the documents that  7 I saw that said that, yes.  8 Q. Isn't it true though, sir,  9 that a SOM analyst could still pull  10 current data from MicroStrategy when he  11 or she was reviewing an order?  12 A. Again, it wasn't the reason  13 that I was making the comment.  14 The comment that I was  15 making about was the fact that it looked  16 like there was a problem with the system  17 and how is the system being addressed.  18 Q. Well, an order flags on the  19 IRR, right?  20 A. Right.  21 Q. Then an analyst can go look  22 at a Store Metric report, correct?  23 A. Yes.  24 Q. And that's a snapshot in</p>	<p style="text-align: right;">Page 811</p> <p>1 A. That is correct.  2 Q. And so these due diligence  3 files relate to a period in time after  4 the Store Metrics report became  5 available, correct?  6 A. That is correct.  7 Q. And they do reflect -- both  8 of them do reflect a SOM analyst going to  9 MicroStrategy to pull current dispensing  10 data, correct? It's the last page of  11 each exhibit.  12 A. I know that.  13 Q. I was trying to help you  14 out, sir.  15 A. I appreciate that. All I  16 can tell is it was pulled from the  17 pharmacy data warehouse and the report  18 was run on 12/10/2013 from the document  19 that I'm looking at.  20 Q. You're looking at  21 Exhibit 20?  22 A. Am I looking at the wrong  23 exhibit?  24 Q. No, no, no. I just want --</p>
<p style="text-align: right;">Page 810</p> <p>1 time of pharmacy and dispensing data  2 related to that particular store for that  3 particular product, correct?  4 A. Correct.  5 Q. But then the analyst can  6 also go a step further and look at  7 MicroStrategy to examine the current  8 data. Would you agree with that?  9 A. Again, I don't recall the  10 full process at this point, and I'd need  11 to see a document showing the process. I  12 just -- I just don't recall it.  13 Q. I'm glad you asked that,  14 because if you go back to Page 179, you  15 note that the Store Metrics were  16 delivered at the end of 2012.  17 Do you see that?  18 A. That's -- the documents that  19 I saw, that's what they said.  20 Q. And the due diligence files  21 that we just looked at, the two exhibits,  22 Whitelaw 19 and 20, were dated  23 December 2013 and February 2014; is that  24 correct?</p>	<p style="text-align: right;">Page 812</p> <p>1 A. I'm looking at Exhibit 20.  2 Q. Okay. And the dates of the  3 dispensing quantities are -- go up to  4 December 6th of 2013. That's the first  5 row, correct?  6 A. That's what the first row  7 says, yeah.  8 Q. Okay. So would you agree --  9 and I understand that nothing on this  10 page says MicroStrategy. But would you  11 agree that this reflects current  12 dispensing data if the e-mail is dated  13 December 10th, 2013?  14 A. It looks like it's fairly  15 current data, yeah.  16 Q. Okay. Great.  17 A. Again, I don't know what  18 system it was pulled from. I can't tell  19 from reading the document.  20 Q. Understood. Sir, you write  21 on Page 183, that CVS's SOM system had no  22 visibility to the outside vendor orders.  23 Sorry. It's 182.  24 It's the first sentence of</p>



<p style="text-align: right;">Page 813</p> <p>1 the second paragraph.  2 Do you see that?  3 A. I see what I wrote, yeah.  4 Q. Okay. Sir, have you done  5 any analysis on what percentage of HCP  6 orders from CVS retail pharmacies in  7 Cuyahoga and Summit County were placed  8 with OVs?  9 MR. BOGLE: With what?  10 MR. HYNES: OVs.  11 MR. BOGLE: Oh, outside  12 vendors.  13 THE WITNESS: Outside  14 vendors.  15 BY MR. HYNES:  16 Q. I'm sorry. Outside vendors?  17 A. No, I have not.  18 Q. Okay. And so you haven't  19 done any analysis as to whether that  20 percentage changed over time from 2006 to  21 2014?  22 A. No.  23 Q. Okay.  24 A. But what I was looking at</p>	<p style="text-align: right;">Page 815</p> <p>1 aware that the outside vendors had their  2 own SOM systems?  3 A. I am aware that they had own  4 SOM systems.  5 Q. Just turn back a page to  6 Page 181.  7 A. Mm-hmm.  8 Q. You have a table there. And  9 it's titled "Summary of Aaron Burtner LP  10 Analyst Time Studies (June-July 2012)."  11 Do you see that?  12 A. I do.  13 Q. And right above that, you  14 write, "Below is a chart showing a  15 representative 12 days in 2012 which  16 demonstrates how few orders were sent for  17 investigation across Mr. Burtner's five  18 distribution centers."  19 Do you see that?  20 A. I do.  21 Q. Okay. First, you say  22 Mr. Burtner's five distribution centers.  23 So you are aware at the time that CVS had  24 about ten distribution centers that</p>
<p style="text-align: right;">Page 814</p> <p>1 here again was the process, and the fact  2 that the -- by not being able to see the  3 outside vendors and combining them with  4 the inhouse distribution, you don't get a  5 complete picture of what's going on for  6 an individual customer, in this case, an  7 individual store. You need both sets of  8 data to actually understand the picture.  9 Q. So is it your belief that a  10 SOM analyst doing diligence on an order  11 could not see what a store was ordering  12 from an outside vendor?  13 A. I'm saying based on what I  14 read in the record, they were not able to  15 do so until sometime after 2013, was what  16 I understood.  17 Q. So you understood that -- I  18 just want to make sure this is clear.  19 Not until sometime after 2013 could a SOM  20 analyst see what a store was ordering  21 from an outside vendor. That's your  22 understanding?  23 A. That was my understanding.  24 Q. Okay. Sir, you're also</p>	<p style="text-align: right;">Page 816</p> <p>1 were -- that were distributing controlled  2 substances to CVS retail pharmacies?  3 A. I am.  4 Q. And that Mr. Burtner  5 reviewed the IRR for half of those  6 distribution centers?  7 A. Well, if there were ten, as  8 you represent, yes. Five is half of ten.  9 So, yes.  10 Q. Okay. And then you say a  11 representative 12 days. Did you choose  12 those 12 days that you put in here.  13 When?  14 And I say that, did you  15 choose the time studies for those --  16 these 12 days?  17 A. Did I choose the time  18 studies? I pulled this from an exhibit,  19 a -- a deposition exhibit from  20 Mr. Burtner. So I believe they were  21 already chosen for his deposition. I was  22 pulling the actual exhibit.  23 Q. Okay. So --  24 A. And the exhibit is listed</p>

<p style="text-align: right;">Page 817</p> <p>1 here. I pulled these studies, yes. 2 Q. Okay. 3 A. I asked for them. 4 Q. And these were all the ones 5 that were used in his deposition, 6 correct? 7 A. Yes. To the best of my 8 knowledge. 9 Q. So these are the ones that 10 the plaintiffs' counsel selected to use 11 in his deposition? 12 A. I believe that is an 13 accurate representation. 14 Q. And Mr. Goetz did that 15 deposition, right? 16 A. I don't know who -- I don't 17 recall who was at that deposition. 18 Q. Okay. Did you review time 19 studies for any other day besides these 20 12 days? 21 A. I honestly can't recall. I 22 honestly don't remember. 23 Q. So can you tell me what 24 makes these 12 a representative sample?</p>	<p style="text-align: right;">Page 819</p> <p>1 Q. If you don't recall, you 2 don't recall. 3 A. I don't recall. 4 Q. Did you review the IRRs 5 related to these time studies? 6 A. Again, I don't recall. 7 Q. So you don't know how many 8 pages the IRRs were -- 9 MR. BOGLE: Object to form. 10 BY MR. HYNES: 11 Q. -- that these time studies 12 relate to? 13 MR. BOGLE: Object to form. 14 THE WITNESS: Again, as I 15 said, I don't recall. 16 BY MR. HYNES: 17 Q. Okay. You don't know how 18 many total orders are reflected in those 19 IRRs? 20 MR. BOGLE: Object to form. 21 THE WITNESS: Again, I don't 22 recall. 23 BY MR. HYNES: 24 Q. Okay. Do you think at any</p>
<p style="text-align: right;">Page 818</p> <p>1 A. Other than being a 2 representative sample of a certain period 3 in time, they are just a sample. 4 Q. So you don't know how these 5 12 were selected from the broader 6 collection of time studies? 7 A. I don't recall. 8 Q. So it's possible that you -- 9 you might have selected these 12 from the 10 larger category? 11 MR. BOGLE: Object to form. 12 THE WITNESS: Again, as I 13 said to you, I asked for time 14 studies and I reviewed those time 15 studies. Now I'm trying to 16 remember -- I don't remember how 17 I -- exactly how they ended up in 18 the table that I put together, I'm 19 sorry. 20 BY MR. HYNES: 21 Q. No, no, that's fair. That's 22 fair. 23 A. At this point I can't get 24 you there.</p>	<p style="text-align: right;">Page 820</p> <p>1 point in time you knew? 2 A. I'm afraid I can't answer 3 your question. I don't recall. 4 Q. Did you make an attempt to 5 investigate the IRRs that these time 6 studies relate to? 7 A. I'm sure I did. I don't 8 recall specifically. So you're asking me 9 to speculate. I don't -- I don't have a 10 list of everything I looked at or 11 everything I -- haven't -- you know, 12 below. 13 But yes, I normally would 14 have tried to look for additional data. 15 But I don't -- can't tell you 16 specifically, I'm sorry. 17 Q. If you had looked at them, 18 would they be cited in your report? 19 A. Again, if they were relevant 20 to the report I would have cited them. 21 They certainly would have been in the 22 reliance list. 23 MR. HYNES: All right. I'll 24 pass the witness. And I'll just</p>

<p style="text-align: right;">Page 821</p> <p>1 state on the record as other  2 defendants have said: I do have a  3 lot more questions for you. My  4 time is limited. So I do reserve  5 my right to seek more time. Thank  6 you for your time today.  7 THE VIDEOGRAPHER: Going off  8 the record. The time is 2:14 p.m.  9 (Short break.)  10 THE VIDEOGRAPHER: We are  11 back on the record at 2:29 p.m.  12 - - -  13 EXAMINATION  14 - - -  15 BY MR. DAVISON:  16 Q. Good afternoon,  17 Dr. Whitelaw. My name is William  18 Davison. I represent Mallinckrodt in  19 this matter, which is one of the entities  20 that you wrote your report on.  21 As we're getting towards the  22 end of the day and it's Friday night, I'm  23 going to try and help make this as  24 efficient as possible.</p>	<p style="text-align: right;">Page 823</p> <p>1 sample programs involved the delivery of  2 samples to healthcare professionals, like  3 physicians, nurse practitioners, and  4 physician assistants; is that correct?  5 A. Yeah, that's what I said.  6 Q. You testified that this was  7 delivered by sales representatives to  8 those healthcare professionals, correct?  9 A. On the sample -- on the  10 programs I worked on, yes.  11 Q. And so just to confirm, your  12 compliance work there was helping to  13 establish a compliant procedure for the  14 sales representatives to provide samples  15 to healthcare providers.  16 A. No. I think that  17 underrepresents the work that I did. It  18 wasn't just a procedure. It was a  19 process. And to also investigate  20 outliers, to investigate data as it came  21 up, to the -- the equivalent of what  22 we've been talking about all day is due  23 diligence. But due diligence on the  24 sample side, et cetera. So it was</p>
<p style="text-align: right;">Page 822</p> <p>1 So I'm going to mark  2 Exhibit 21, which is simply another copy  3 of your appendix of materials considered.  4 I'm hopeful that way we won't have to be  5 flipping back and forth as we're looking  6 at things as we go through. Does that  7 make sense to you?  8 A. That does make sense to me.  9 Q. All right. We'll try and  10 save some time.  11 (Document marked for  12 identification as Exhibit  13 Whitelaw-21.)  14 BY MR. DAVISON:  15 Q. So, Dr. Whitelaw, a few  16 clarifying questions that I wanted to  17 talk to you about with respect to your  18 qualifications.  19 As you mentioned yesterday  20 that you have past compliance experience  21 in designing sample programs for  22 noncontrolled substances, correct?  23 A. That is what I said, yes.  24 Q. And you testified that these</p>	<p style="text-align: right;">Page 824</p> <p>1 working on the entire process, not just a  2 procedure.  3 Q. Fair enough. So it's  4 broader than a procedure. And I guess my  5 question was more focused. One of the  6 goals of the processes that you were  7 creating was to ensure that there was a  8 compliant way for sales representatives  9 to provide the samples to healthcare  10 providers, correct?  11 A. Yes, including preventing --  12 obviously the goal being to prevent  13 samples going astray, a/k/a diversion.  14 Q. Of course. And in designing  15 this compliance program, did you consult  16 OIG guidance?  17 A. I'm sure I did.  18 Q. And you would have consulted  19 OIG advisory opinions?  20 A. I would have consulted any  21 relevant guidance at the time, yes.  22 Q. That could include corporate  23 integrity agreements?  24 A. It could.</p>

<p style="text-align: right;">Page 825</p> <p>1 Q. And would it include  2 settlements?  3 A. It could.  4 Q. And, sir, speaking of OIG,  5 are you aware that the OIG provided  6 guidance for compliance programs for  7 physicians in 2000?  8 A. Yes, I am.  9 Q. Did you consult it for the  10 sample programs that you would have --  11 the sample compliance programs that you  12 would have designed?  13 A. Honestly I don't remember  14 everything that I looked at at that time.  15 It's been a while.  16 Q. Okay. Did you consult this  17 when you wrote your report?  18 A. I'm sorry.  19 Q. By this -- apologies.  20 A. Please.  21 Q. Did you consult the OIG  22 guidance for compliance programs for  23 physicians dated from 2000 in writing  24 your report?</p>	<p style="text-align: right;">Page 827</p> <p>1 SOMs expert.  2 Q. And prior to your  3 discussions with Mr. Rafalski, all of the  4 documents that you reviewed for this  5 litigation, all of the deposition  6 transcripts, all of that work that you  7 did for this litigation, would you have  8 considered yourself a suspicious order  9 monitoring expert?  10 MR. BOGLE: Object to form.  11 THE WITNESS: Could you be  12 more -- again, could you repeat  13 the question? I'm sorry. It's  14 been a long day.  15 BY MR. DAVISON:  16 Q. Understood, sir. So prior  17 to the work that you did for this  18 litigation, which we've discussed  19 included reviewing, you know, hundreds of  20 thousands of documents, deposition  21 transcripts, discussions with  22 Mr. Rafalski, did you consider yourself a  23 suspicious order monitoring expert?  24 MR. BOGLE: Same objection.</p>
<p style="text-align: right;">Page 826</p> <p>1 A. I did look at it. It's  2 footnoted in my report. So obviously I  3 did look through it and look at it, yes.  4 Q. All right. So the  5 compliance program for physicians is  6 footnoted in your report is your  7 recollection?  8 A. It is.  9 Q. Okay. Thank you. Now, you  10 stated just a little while ago to  11 Mr. Hynes that you've never operated or  12 audited a suspicious order monitoring  13 system; is that correct?  14 A. That is what I told him,  15 yes.  16 Q. Okay. Do you consider  17 yourself an expert on suspicious order  18 monitoring?  19 A. I believe, based on the work  20 that I have done, my 30 years'  21 experience, all that I have reviewed, all  22 the DEA guidance I have reviewed, my  23 conversations with Mr. Rafalski, yes, I  24 would say that I am qualified to be a</p>	<p style="text-align: right;">Page 828</p> <p>1 THE WITNESS: Honestly, I  2 don't rightly recall if I ever  3 thought of it in those terms.  4 BY MR. DAVISON:  5 Q. So your answer is that you  6 never really thought about it one way or  7 another --  8 A. I'm a compliance expert.  9 Q. -- whether you were a  10 suspicious order monitoring -- excuse me.  11 Sorry.  12 A. Sorry.  13 Q. She's going to -- it's late  14 for her as well, so.  15 A. Apologies.  16 Q. No problem.  17 So you didn't think of it  18 one way or another as to whether you were  19 a suspicious order monitoring expert?  20 MR. BOGLE: Object to form.  21 Asked and answered.  22 THE WITNESS: As I said, I  23 don't recall. Again, I'm a  24 compliance expert. I work in a</p>

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1 variety of different areas. I'm  
2 not sure that I reflected on it  
3 the way you're asking me to.  
4 BY MR. DAVISON:  
5 Q. Okay. Prior to this  
6 litigation, have you ever held yourself  
7 out to a potential client as a suspicious  
8 order monitoring expert?  
9 A. Other than the work that I  
10 did on a proposal for Deloitte, which,  
11 again, was more of a compliance process  
12 assessment for suspicious order  
13 monitoring program, I don't recall ever  
14 putting that moniker on my name.  
15 Q. So you didn't tell Henry  
16 Schein that you were an -- that you were  
17 an expert in suspicious order monitoring  
18 when you made that pitch, correct?  
19 MR. BOGLE: Objection.  
20 Misstates testimony.  
21 THE WITNESS: As I said, I  
22 think I answered your question as  
23 best I can. I don't have anything  
24 else to add to that answer.

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1 BY MR. DAVISON:  
2 Q. All right. So I think you  
3 said, "I don't recall ever putting that  
4 moniker on my name." Is that accurate?  
5 MR. BOGLE: That's part of  
6 his answer.  
7 THE WITNESS: That was part  
8 of my answer.  
9 BY MR. DAVISON:  
10 Q. Okay. Sir, you are  
11 providing an opinion regarding the  
12 relevant standards surrounding the  
13 design, implementation, and operation of  
14 corporate and controlled substances  
15 compliance programs for the  
16 pharmaceutical industry; is that correct?  
17 A. Can you --  
18 Q. If you want to look, I'm  
19 on -- I'm on Page 2 --  
20 A. Where are we?  
21 Q. -- of your report. Just  
22 taking what you say your scope is.  
23 A. No, I know. I'm just asking  
24 where you are. That's helpful for me.

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1 Okay. Where are you now?  
2 Q. I'm on Page 2. If you look  
3 at Number 1 under scope.  
4 A. Number 1 under scope, okay.  
5 Q. So I'm going to repeat the  
6 question. You were providing an opinion  
7 regarding the relevant standards  
8 surrounding the design, implementation  
9 and operation of corporate and controlled  
10 substances compliance programs for the  
11 pharmaceutical industry; is that  
12 accurate?  
13 A. That's what it says.  
14 Q. Was that what you are  
15 providing an opinion on?  
16 A. Yes.  
17 Q. Okay. You were also  
18 providing an opinion regarding the  
19 application of those standards to  
20 manufacturers and distributors of  
21 controlled substances, correct?  
22 A. That is correct.  
23 Q. You also are providing an  
24 opinion on the effectiveness of the

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1 compliance programs for five distributors  
2 and one manufacturer of prescription  
3 opioid medicinal products based upon  
4 available documentation from 1996 to  
5 2018, correct?  
6 A. That is also correct.  
7 Q. Did plaintiffs' counsel  
8 select the five distributors and one  
9 manufacturer on which you wrote your  
10 report?  
11 MR. BOGLE: Objection.  
12 THE WITNESS: These were the  
13 ones that they asked me to do a  
14 review of, yes.  
15 BY MR. DAVISON:  
16 Q. The only manufacturer for  
17 which you are providing an opinion on the  
18 effectiveness of its compliance program  
19 is Mallinckrodt, correct?  
20 A. I was only asked to look at  
21 Mallinckrodt.  
22 Q. Well, sir, my question is a  
23 little bit different. The only  
24 manufacturer for which you are providing



<p style="text-align: right;">Page 833</p> <p>1 an opinion on the effectiveness of its 2 compliance program is Mallinckrodt, 3 correct?</p> <p>4 A. Mallinckrodt is the only 5 manufacturer in my report, sir.</p> <p>6 Q. So the answer to that 7 question is yes?</p> <p>8 A. The answer to that question 9 is yes.</p> <p>10 Q. Thank you. You do not 11 intend to offer an opinion at this time 12 regarding any other manufacturer's 13 compliance program, correct?</p> <p>14 A. Not at this time.</p> <p>15 Q. You do not intend to offer 16 an opinion regarding the application of 17 your opinions regarding the standards 18 surrounding the design, implementation, 19 and operation of controlled substances 20 compliance programs to any other 21 manufacturers program at this time, 22 correct?</p> <p>23 MR. BOGLE: Object to form. 24 BY MR. DAVISON:</p>	<p style="text-align: right;">Page 835</p> <p>1 Q. But you didn't review their 2 suspicious order monitoring program, 3 correct?</p> <p>4 A. No. There's no review of 5 another manufacturer's suspicious order 6 monitoring program in my report.</p> <p>7 Q. All right. So I think I 8 have an understanding of kind of the 9 opinions at a high level. I'd like to 10 discuss just a couple of questions 11 regarding opinions you're not offering. 12 Okay?</p> <p>13 A. Sure.</p> <p>14 Q. So you stated earlier today 15 that you're here as a compliance expert, 16 so you are not drawing legal conclusions, 17 correct?</p> <p>18 A. Yes, sir, that is correct.</p> <p>19 Q. So you're not offering a 20 legal conclusion as to whether any 21 defendant violated the Controlled 22 Substances Act, correct?</p> <p>23 A. That is correct.</p> <p>24 Q. You are not offering a legal</p>
<p style="text-align: right;">Page 834</p> <p>1 Q. Do you want me to start 2 again?</p> <p>3 A. Yeah, and read it a bit 4 slower or at least give me something to 5 look at it because that's an awful lot 6 of -- that's a whole mouthful of words.</p> <p>7 Q. Let's -- we'll strike that 8 one.</p> <p>9 You do not intend to offer 10 any opinions regarding any other 11 manufacturer defendant in this litigation 12 at this time, correct?</p> <p>13 A. Not at this time.</p> <p>14 Q. And there is nothing in your 15 report regarding any other manufacturer 16 of controlled substances other than 17 Mallinckrodt, correct?</p> <p>18 MR. BOGLE: Object to form.</p> <p>19 THE WITNESS: No, I think 20 that's inaccurate. There are a 21 couple references in my report to 22 Endo and Purdue up in the front of 23 the report.</p> <p>24 BY MR. DAVISON:</p>	<p style="text-align: right;">Page 836</p> <p>1 conclusion as to whether any defendant 2 violated the SOM regulation?</p> <p>3 A. Correct.</p> <p>4 Q. And when you were questioned 5 earlier today by Cardinal's counsel, you 6 stated that the question of whether any 7 of Cardinal's products were diverted was 8 outside the scope of your report.</p> <p>9 Is the same true for 10 Mallinckrodt's products?</p> <p>11 A. The same holds true for 12 Mallinckrodt, yes.</p> <p>13 Q. And is the same true for all 14 of the distributors and manufacturers in 15 your report's box?</p> <p>16 A. Could you give me the 17 question again, please?</p> <p>18 Q. Yes. No problem.</p> <p>19 Understood.</p> <p>20 With respect to Cardinal 21 earlier today, you stated that the 22 question of whether any product was 23 diverted was outside the scope of your 24 report. Is the same true for all of the</p>

<p style="text-align: right;">Page 837</p> <p>1 distributors, pharmacies and 2 manufacturers that you reviewed? 3 A. Again, as I said, same thing 4 for Cardinal I would say for every other 5 defendant is the same. I looked at the 6 policies and the process and the systems, 7 and that is what I'm rendering my -- my 8 opinions on. 9 Q. So the answer to that is 10 yes? 11 A. The answer to that is I'm 12 not making statements about whether any 13 particular order was diverted or not 14 diverted. 15 Q. Thank you, sir. 16 Now, sir, in evaluating the 17 effectiveness of Mallinckrodt's 18 compliance program, you utilized the 19 methodology that have used -- that you 20 have used during the last 30 years when 21 auditing or investigating compliance 22 issues; is that correct? 23 A. I think that's a fair way of 24 characterizing it, yes.</p>	<p style="text-align: right;">Page 839</p> <p>1 BY MR. DAVISON: 2 Q. Are you familiar with OIG 3 toolkits and resources like RAT-STATS to 4 select random samples? 5 A. I am familiar with what 6 those are, yes. 7 Q. Okay. And that's a way to 8 select random samples of data or 9 documents for review, correct? 10 A. But it's not a way of 11 utilizing and looking at process systems 12 and process and controls for compliance 13 programs, per se. That's not how we 14 do -- that's not how I do that, no. 15 Q. So when you're looking at 16 processes and controls for compliance 17 programs, you do not use random sampling? 18 A. No. I actually ask you what 19 the standards are that you're doing and 20 how are you working against those 21 standard and show me how those are 22 actually working. 23 Q. Okay. So talking about what 24 you specifically reviewed today and as</p>
<p style="text-align: right;">Page 838</p> <p>1 Q. So I want to -- I want to 2 understand a little bit more about the 3 methodology that you've used in your 4 30 years of experience. 5 A. Sure. 6 Q. What is your practice 7 generally when you select data or 8 documents for a sample? 9 MR. BOGLE: Object to form. 10 Vague and ambiguous. 11 BY MR. DAVISON: 12 Q. Let me see if I can narrow 13 it down for you. I'll withdraw that 14 question. 15 A. That would be real helpful. 16 Q. No problem. 17 Generally in your 18 experience, when you're selecting data or 19 documents to review, do you do a random 20 sample? 21 MR. BOGLE: Object to form. 22 THE WITNESS: You're still 23 going to have to narrow it down 24 further.</p>	<p style="text-align: right;">Page 840</p> <p>1 part of your methodology. It's fair to 2 say that you reviewed a number of 3 standard operating procedures; is that 4 correct? 5 A. I reviewed a number of 6 documents that were supposed -- that were 7 purported to be standard operating 8 procedures or draft standard operating 9 procedures, yes. 10 Q. And you also reviewed 11 e-mails for each of the individual 12 manufacturers, distributors, pharmacies, 13 that you looked at, internal e-mails? 14 A. E-mails were part of it. 15 Q. And generally, in your 16 compliance history, one way of gaining 17 information would be to interview 18 employees of a client, correct? 19 A. That is one way to do it, 20 yes. 21 Q. And -- and here I understand 22 there weren't interviews, but you 23 reviewed deposition transcripts. Is that 24 fair?</p>

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1 A. That is fair. But in the  
2 same way that I interviewed, just so we  
3 are completely clear, that I would have  
4 interviewed Mallinckrodt employees if I  
5 were working -- Mallinckrodt was my  
6 direct client. I worked through  
7 plaintiffs and plaintiffs' counsel and  
8 interviewed them the same way, saying  
9 this is what I'm looking for, these are  
10 the documents I need to do my review,  
11 this is what I'm looking for.  
12 It's the same kind of  
13 conversation. When I got them, review  
14 them, and I look at them and, you know,  
15 again, ask for clarifying questions, ask  
16 for clarifying documents, et cetera. So  
17 it's the same methodology.  
18 Q. All right. So generally the  
19 same methodology. And -- and another  
20 piece that -- that you'd review would be  
21 correspondence with regulatory or  
22 government agencies, correct?  
23 A. That is correct.  
24 Q. All right. And you'd agree

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1 with me that all of these pieces are  
2 important when you're evaluating the  
3 compliance program of a client?  
4 A. I would say all the -- all  
5 the general categories of documents we  
6 are talking about are important, yes.  
7 Q. So for example, you can't  
8 just review a company's standard  
9 operating procedures, because you  
10 wouldn't know how the standard operating  
11 procedures were being applied?  
12 A. I would say that's an  
13 accurate statement. You're looking for  
14 not only what did you write down, but  
15 what are you doing in practice.  
16 Q. So reviewing standard  
17 operating procedures alone wouldn't be  
18 sufficient to draw a conclusion relating  
19 to a client's compliance program?  
20 A. Well, it would certainly be  
21 sufficient to draw a conclusion about a  
22 complying -- compliance program's written  
23 standards section, yes. If you're asking  
24 me do I think it's sufficient to draw

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1 about an entire compliance program, no.  
2 I think you need to look at more.  
3 Q. And with respect to the work  
4 that you did here, which is to look, as I  
5 understand, at the anti-diversion  
6 compliance programs for the -- the  
7 defendants at issue here, it wouldn't be  
8 sufficient, correct?  
9 MR. BOGLE: Object to form.  
10 THE WITNESS: It wouldn't be  
11 sufficient. Could you be clear  
12 what you mean by "it"?  
13 BY MR. DAVISON:  
14 Q. Solely reviewing standard  
15 operating procedures.  
16 MR. BOGLE: Object to form.  
17 THE WITNESS: Again, we're  
18 talking about a type of compliance  
19 program. So the same way of doing  
20 it and same document -- types of  
21 documents you would be looking  
22 for. It'd almost translate all  
23 the way down the line as we've  
24 discussed, we'd be looking at it

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1 in the same way.  
2 BY MR. DAVISON:  
3 Q. So I -- I think your answer  
4 was that solely reviewing standard  
5 operating procedures would not be  
6 sufficient alone.  
7 MR. BOGLE: Object to form.  
8 THE WITNESS: Would --  
9 again, to -- to be precise, would  
10 not be sufficient alone to judge  
11 the entire program. But is  
12 sufficient to judge the written  
13 standard section of the program,  
14 yes.  
15 BY MR. DAVISON:  
16 Q. Dr. Whitelaw, you mentioned,  
17 I think multiple times, and I apologize  
18 for bringing this back up. But you had  
19 consulted with James Rafalski in writing  
20 your report, correct?  
21 A. That is what I've stated.  
22 Q. So I do have a couple of  
23 individual questions for Mallinckrodt.  
24 Did you and Mr. Rafalski

<p style="text-align: right;">Page 845</p> <p>1 discuss any specific topics or issues  2 related to Mallinckrodt?  3 A. No, not that I recall. I do  4 not believe we talked about Mallinckrodt  5 at all.  6 Q. So you didn't discuss with  7 Mr. Rafalski the DEA's investigation of  8 Mallinckrodt's SOM program?  9 A. No, sir. We did not talk  10 about that. We talked in general  11 terms -- so we can be clear. He and I  12 had general conversations about a  13 manufacturer's SOMs program. And sort of  14 a discussion around, you know, discussing  15 the distributor's program and a  16 manufacturer's program, how DEA looks at  17 them, you know, each one, a general  18 approach. But we did not get into the  19 specifics --  20 Q. Was --  21 A. -- regarding Mallinckrodt.  22 Q. Excuse me. I apologize.  23 A. We did not get into  24 specifics regarding Mallinckrodt.</p>	<p style="text-align: right;">Page 847</p> <p>1 with me that generally a controlled  2 substance travels through that system  3 from a manufacturer to a distributor or  4 wholesaler, then to the pharmacy, and  5 then it's to the patient based on a  6 prescription by a physician?  7 A. Generally, the only caveat  8 that I would add is by someone licensed  9 to prescribe a controlled substance. And  10 let's be clear, it can be more than a  11 physician.  12 Q. Fair enough. And, sir, are  13 you aware that manufacturer registrants  14 generally sell their product to  15 wholesalers, distributors, or to  16 distributing chain pharmacies?  17 A. In general, yes.  18 Q. What do you mean by in  19 general, sir?  20 A. I'm sure there are  21 exceptions. You said -- you asked me,  22 was I generally aware. I answered your  23 question.  24 Q. All right. So would you</p>
<p style="text-align: right;">Page 846</p> <p>1 Q. Was Mr. Rafalski aware that  2 the only manufacturer for which you are  3 conducting a review was Mallinckrodt?  4 A. I have no idea what he --  5 what he was aware of not aware of.  6 Q. Did Mr. Rafalski suggest any  7 particular Mallinckrodt documents that  8 you should review?  9 MR. BOGLE: Object to form.  10 THE WITNESS: Again, I think  11 I tried to make it as clear as I  12 can. We did not discuss  13 Mallinckrodt in specifics at all.  14 We talked about manufacturers'  15 SOMs programs and distributor SOMs  16 programs to the best of my  17 recollection.  18 BY MR. DAVISON:  19 Q. All right. So, sir,  20 yesterday you talked about the closed  21 system of distribution for controlled  22 substances, correct?  23 A. We touched on it, yes.  24 Q. All right. Would you agree</p>	<p style="text-align: right;">Page 848</p> <p>1 agree with me that generally a  2 manufacturer doesn't sell to individual  3 pharmacies?  4 A. Only indirectly. If you're  5 saying from the wholesaler to the  6 pharmacy, your product travels down that  7 pipeline, that I would say is a general  8 statement.  9 Q. Okay. So you said only  10 indirectly. I guess I just want to make  11 this clear. A manufacturer sells to the  12 wholesaler, correct?  13 A. Right. That's what I mean  14 by indirect.  15 Q. But they are not selling it  16 to the pharmacy?  17 A. They're selling it to the  18 wholesaler who's then in turn filling the  19 orders coming from the pharmacy. That  20 was the discussion that we just had, yes.  21 Q. Okay. Correct. I was just  22 trying to be clear on the selling  23 indirectly, what you mean by that?  24 A. That's what I meant by that.</p>

<p style="text-align: right;">Page 849</p> <p>1 Q. Okay. Sir, I'm going to  2 turn to Page 36 of your report.  3 A. Of course.  4 Q. Thank you. If you look at  5 Section B of your report.  6 A. Mm-hmm.  7 Q. You write, "For a  8 manufacturer's anti-diversion program, I  9 would expect to see."  10 Did I read that correctly?  11 A. You did.  12 Q. All right. And you list  13 four separate headings with some  14 sub-bullets underneath them, correct?  15 A. Yes, actually, I did.  16 Q. And, sir, there's no  17 citations in this section of your report,  18 correct?  19 MR. BOGLE: Objection.  20 Asked and answered previously.  21 But you can answer again.  22 THE WITNESS: There are no  23 footnotes here, no.  24 BY MR. DAVISON:</p>	<p style="text-align: right;">Page 851</p> <p>1 that's explicitly stated within the  2 Controlled Substances Act, correct?  3 MR. BOGLE: Object to form.  4 THE WITNESS: Either that --  5 again, I need you to be more  6 clear, because as far as I'm  7 concerned, what I would expect to  8 see for a good compliance program  9 in this area, an anti-diversion  10 program, and these attributes are  11 what I see is embedded in the  12 overall concept of having an  13 effective -- an effective  14 anti-diversion program. So...  15 BY MR. DAVISON:  16 Q. And so that's why I said  17 explicitly. So I understand your view is  18 that these are implicit in having  19 effective controls against diversion,  20 those four words.  21 It's not explicitly listed  22 that a manufacturer must know their  23 customer within that statute, correct?  24 MR. BOGLE: Object to form.</p>
<p style="text-align: right;">Page 850</p> <p>1 Q. And you said earlier that  2 generally if there was a document that  3 supported your proposition, you would  4 footnote it in your report, correct?  5 MR. BOGLE: Object to form.  6 THE WITNESS: Again, I'm  7 still not sure what -- I did  8 not -- there are no footnotes  9 here, if that's what you're asking  10 me. There are no footnotes right  11 here.  12 BY MR. DAVISON:  13 Q. So going through these,  14 you're not claiming that each of these  15 expectations that you've laid out here is  16 something that's explicitly stated within  17 the Controlled Substances Act, correct?  18 (Brief interruption.)  19 BY MR. DAVISON:  20 Q. I'll repeat the question for  21 you.  22 A. Thank you.  23 Q. So going through each of  24 these expectations, it's not something</p>	<p style="text-align: right;">Page 852</p> <p>1 THE WITNESS: If you're  2 asking me are those words in the  3 statute? Is that the question?  4 BY MR. DAVISON:  5 Q. That's what I'm asking you.  6 Yes.  7 A. No, they're not.  8 Q. Okay. And if any of the  9 words that are here under your  10 expectations were in the Controlled  11 Substances Act statute, you would have  12 cited to it, correct?  13 MR. BOGLE: Objection to  14 form.  15 THE WITNESS: It would have  16 been cited somewhere in the  17 report, yes.  18 BY MR. DAVISON:  19 Q. Well, generally good  20 scholarship is to cite to what you're  21 actually -- within the report, correct?  22 MR. BOGLE: Object to form.  23 THE WITNESS: And if you  24 note it, I do cite by section.</p>



<p style="text-align: right;">Page 853</p> <p>1 And then you'll notice there are 2 discussions before each of the 3 sections of attributes, which is 4 how it was organized. And I 5 believe we did have that 6 discussion yesterday. 7 BY MR. DAVISON: 8 Q. Yeah, I'm referring to a 9 separate section. No one talked about 10 this section yesterday. 11 A. I understand that. I'm 12 saying the way this whole part of the 13 report was organized, there is a general 14 discussion up front, the citations, and 15 then there are the attributes that are 16 listed. And there are not -- as we have 17 covered, there are not footnotes here. 18 Q. So I can go back to the 19 earlier sections in your report and I'll 20 find where these expectations come from, 21 correct? 22 A. You will see where those 23 concepts and expectations come from. 24 Q. Got it. And that's based on</p>	<p style="text-align: right;">Page 855</p> <p>1 A. Yes. That's what I say. 2 Q. And again, this is based on 3 all of the pages that lead up to Page 36, 4 correct? 5 MR. BOGLE: Object to form. 6 THE WITNESS: That, plus my 7 expectation, plus my discussions 8 with Mr. Rafalski, plus my review 9 of all the documents in this case. 10 BY MR. DAVISON: 11 Q. Sir, have you seen -- strike 12 that. 13 You're aware that DEA 14 conducts audits of distributors, correct? 15 A. Yes, I'm aware of that. 16 Q. All right. And that DEA 17 reviews distributors' SOM programs, 18 correct? 19 MR. BOGLE: Object to form. 20 THE WITNESS: Yes, I'm aware 21 of that as well. 22 BY MR. DAVISON: 23 Q. And that DEA reviews 24 distributors' anti-diversion controls?</p>
<p style="text-align: right;">Page 854</p> <p>1 your review of the guidance, your 2 experience, and your review of all the 3 documents that we've been discussing for 4 the past two days? 5 A. Correct. And my 6 conversation with Mr. Rafalski, et 7 cetera. It's the whole kit and caboodle. 8 Q. All right. I'm going to 9 understand these -- because we don't have 10 anything specific, I'm just going to call 11 these Dr. Whitelaw's expectations for a 12 good program. All right? 13 Starting with "know your 14 customer," you write, "The manufacturer 15 has and retains current granular and 16 specific knowledge about each distributor 17 of its controlled substance and their 18 unique circumstances including all the 19 information outlined in the distributor 20 section." 21 And then you state, "The 22 manufacturers should conduct distributor 23 site visits to review the distributors' 24 anti-diversion controls," correct?</p>	<p style="text-align: right;">Page 856</p> <p>1 A. From time to time, yes. 2 Q. All right. So 3 Dr. Whitelaw's expectation is that 4 manufacturers conduct reviews and audits 5 of distributors on top of what DEA does, 6 correct? 7 MR. BOGLE: Object to form. 8 THE WITNESS: They -- they 9 are your customers. You should be 10 aware of what they are doing and 11 comfortable with the way they are 12 acting. That is just good 13 third-party management, which is 14 part of an effective compliance 15 program. 16 Again, when you go back to 17 the federal sentencing guidelines, 18 the front of the report, if we 19 really want to discuss it in 20 detail, yeah, my expectation was 21 that you manage your own third 22 parties as well and not just 23 simply rely on the DEA. 24 BY MR. DAVISON:</p>

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1 Q. And --  
 2 A. The DEA gives you a piece of  
 3 information and it's information that you  
 4 should take into account. But it  
 5 doesn't -- it doesn't extract  
 6 Mallinckrodt from the requirement that it  
 7 should go out and make sure that the  
 8 people that it's selling its products to  
 9 are behaving in a way it expects them to  
 10 behave.  
 11 Q. Your expectation, sir, is  
 12 that manufacturers will hold their  
 13 distributors to a higher standard than  
 14 what DEA does, correct?  
 15 MR. BOGLE: Object to form.  
 16 Misstates his testimony.  
 17 THE WITNESS: You are  
 18 completely misstating what I said.  
 19 I said I expect you to go out and  
 20 look at your customers for the  
 21 products that you're selling and  
 22 ensure yourself that you're  
 23 comfortable with the way they are  
 24 behaving since they are selling

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1 your products. You have a duty to  
 2 oversee those people who you  
 3 contract with.  
 4 BY MR. DAVISON:  
 5 Q. All right, sir. So if DEA  
 6 audits a distributor, gives them a clean  
 7 audit, and a month later Mallinckrodt  
 8 audits the distributor, can Mallinckrodt  
 9 rely on the DEA's audit?  
 10 MR. BOGLE: Objection.  
 11 Vague. Ambiguous. Overly broad.  
 12 THE WITNESS: Would you like  
 13 to explain to me what you mean by  
 14 rely? Because that's a fairly  
 15 broad statement here.  
 16 BY MR. DAVISON:  
 17 Q. So, sir, when -- when you  
 18 advise clients, you don't tell them to  
 19 rely on what the government does?  
 20 MR. BOGLE: Objection.  
 21 THE WITNESS: I don't know  
 22 what you mean by rely. Could you  
 23 please be clearer?  
 24 MR. DAVISON: Strike -- move

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1 to strike the question.  
 2 BY MR. DAVISON:  
 3 Q. All right. You also stated  
 4 that "manufacturers are to utilize where  
 5 appropriate information derived from  
 6 chargeback data," correct?  
 7 A. That is what I state here,  
 8 yes.  
 9 Q. All right. So, sir, what's  
 10 a chargeback?  
 11 A. Well, let's go to my report  
 12 and we can go pull the definition that I  
 13 used in my report, sir --  
 14 Q. Strike that question.  
 15 Sitting here today, without  
 16 looking at your report, can you tell me  
 17 what a chargeback is?  
 18 A. I think to be completely  
 19 clear we should use the definition that's  
 20 in my report. And we can go to that, and  
 21 that's the definition I'm using.  
 22 Q. So, sir, your answer is no?  
 23 MR. BOGLE: Objection.  
 24 Misstates his testimony.

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1 THE WITNESS: I said I'd  
 2 like to go and use the definition  
 3 that I have in my report and make  
 4 it completely accurate for the  
 5 record.  
 6 BY MR. DAVISON:  
 7 Q. So, sir, you are concerned  
 8 that you cannot provide me with an  
 9 accurate definition of a chargeback  
 10 without looking at your report, correct?  
 11 MR. BOGLE: Objection.  
 12 Misstates testimony.  
 13 THE WITNESS: That's not  
 14 what I'm saying.  
 15 BY MR. DAVISON:  
 16 Q. So sitting here today,  
 17 without looking at your report, what is a  
 18 chargeback?  
 19 A. As I said to you, I'm going  
 20 to go to my -- refer to my report and  
 21 tell you the definition that was used --  
 22 that I used in this report.  
 23 Q. All right. Since you can't  
 24 tell me about it, why don't we go to your

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1 report. Tell me what the chargeback is.  
2 MR. BOGLE: That's not what  
3 he said.  
4 Go ahead, go to your report.  
5 THE WITNESS: Okay. We  
6 will.  
7 The definition that I'm  
8 using for chargeback is on  
9 Page 233.  
10 BY MR. DAVISON:  
11 Q. Okay. So what's the  
12 definition?  
13 A. Chargebacks are basically --  
14 "Chargebacks are a common pharmaceutical  
15 tool used by manufacturers to make  
16 distributors whole when they sell  
17 pharmaceuticals to pharmacies at prices  
18 below what the distributor paid to the  
19 manufacturer."  
20 Q. And, sir, have you ever  
21 reviewed chargeback data in your 30 years  
22 of experience?  
23 A. To my knowledge, I honestly  
24 don't remember. I've reviewed a lot of

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1 data over my 30 years' experience. So I  
2 can't tell you whether or not I -- I  
3 can't tell you.  
4 Q. Sir, prior to your  
5 engagement for this litigation, did you  
6 know what a chargeback was?  
7 A. Yes, I knew what a  
8 chargeback was before this.  
9 Q. You are aware that  
10 chargeback data provides a limited subset  
11 of information, correct?  
12 MR. BOGLE: Object to form.  
13 THE WITNESS: Can you define  
14 what you mean by "limited subset  
15 of information"?  
16 BY MR. DAVISON:  
17 Q. Sure. It provides a limited  
18 amount of information relating the actual  
19 sale of the product from the distributor  
20 to the pharmacy.  
21 A. I understand it provides  
22 information about that.  
23 Q. What information does it  
24 provide?

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1 A. Do we need to go into  
2 every -- you know where the product --  
3 you know where the wholesaler is selling,  
4 and the amounts that are being sold to a  
5 particular pharmacy, and you know what  
6 the cost basis is and it's coming back to  
7 you. So you know where your product is  
8 going at the end of the day.  
9 Q. Does Mallinckrodt receive  
10 chargeback data for every sale that a  
11 distributor makes to a pharmacy?  
12 A. No, I don't believe it does.  
13 Q. And sir, just to be clear,  
14 the term "chargeback" is not used in the  
15 Controlled Substances Act -- excuse me.  
16 Strike that.  
17 The term "chargeback" is not  
18 used in the anti-diversion piece of the  
19 Controlled Substances Act, correct?  
20 A. It is not -- those  
21 specific -- that specific term or  
22 specific words are not used.  
23 Q. So again, your view that a  
24 manufacturer needs to look at chargeback

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1 data comes from your reading of the  
2 obligation to maintain effective controls  
3 against diversion, is that fair?  
4 A. It comes from my reading.  
5 It also comes from the administrator's  
6 position in -- in the Masters case and  
7 others, that if you have information that  
8 is potentially useful in operating your  
9 suspicious order monitoring program, you  
10 should be using that information.  
11 Chargeback data is a piece of information  
12 that you have access to that you should  
13 be utilizing.  
14 Q. And just to be clear, you're  
15 not claiming that the Masters decision  
16 stated anything about chargebacks, you're  
17 instead broadening it out to include  
18 chargebacks?  
19 MR. BOGLE: Object to form.  
20 THE WITNESS: I'm broadening  
21 it out to describe what the  
22 administrator, my reading of the  
23 administrator's opinion was. That  
24 if you have information that bears

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<p>1 on diversion, a manufacturer in 2 this case, cannot turn a blind eye 3 to that information, but should 4 utilize that information to the 5 extent possible. 6 BY MR. DAVISON: 7 Q. And, sir, in your 30 years 8 of experience, have you ever advised a 9 pharmaceutical manufacturer to utilize 10 chargeback data in its compliance 11 program? 12 A. Not for the areas that I was 13 looking at at the time, no. But if you 14 wanted it in general terms, I would have 15 advised them to use all available data. 16 I would tell any client to use all 17 available data that's pertinent to the 18 topic we are talking about. 19 MR. DAVISON: Move to strike 20 everything following "I was 21 looking at the time, no." 22 BY MR. DAVISON: 23 Q. Sir, we've -- people have 24 talked with you about the DEA witnesses</p>	<p>1 THE WITNESS: No, actually 2 it wouldn't affect my opinion at 3 all. 4 BY MR. DAVISON: 5 Q. Okay. Now, sir, did you 6 request from plaintiffs' counsel all 7 documents reflecting communications 8 between Mallinckrodt and DEA relating to 9 its suspicious order monitoring and 10 anti-diversion programs? 11 A. Yes, I believe I did. 12 Q. So your expectation is that 13 you've reviewed all the documents 14 reflecting communications between DEA and 15 Mallinckrodt regarding Mallinckrodt's SOM 16 and anti-diversion programs, correct? 17 MR. BOGLE: Object to form. 18 THE WITNESS: No, I think 19 you're overstating what I said. 20 I said -- you asked me did I 21 ask counsel for any -- for the DEA 22 correspondence. I said I did. 23 Then you turned it around 24 and said have I reviewed</p>
Page 866	Page 868
<p>1 that have provided testimony in this 2 case. 3 Do you recall that? 4 A. I recall that. 5 Q. All right. And sir, I think 6 you testified that you reviewed Kyle 7 Wright's deposition transcript. 8 Do you recall that? 9 A. I do recall that. 10 Q. Are you aware that 11 Mr. Wright stated that chargebacks play 12 no role in suspicious order monitoring? 13 MR. BOGLE: Object to form. 14 THE WITNESS: Again, I don't 15 recall it off the top of my head. 16 No, I don't. Do you have a 17 document that you would like me to 18 look at? 19 BY MR. DAVISON: 20 Q. Well, sir, if the DEA says 21 that the chargebacks play no role in 22 suspicious order monitoring, would that 23 affect your opinion at all? 24 MR. BOGLE: Object to form.</p>	<p>1 everything. And the answer is, 2 well, I reviewed everything that 3 they would have had in their files 4 that they provided to me. 5 So if there's something that 6 you haven't given to plaintiffs' 7 counsel, there's no way I could 8 have reviewed that. 9 BY MR. DAVISON: 10 Q. That's completely fair, sir. 11 So let me try to be a little more clear 12 on that. 13 A. Okay. 14 Q. So your expectation is that 15 plaintiffs' counsel provided you with 16 everything in their files that reflected 17 communications between Mallinckrodt and 18 DEA regarding its suspicious order 19 monitoring and anti-diversion program? 20 A. That is my expectation. 21 (Document marked for 22 identification as Exhibit 23 Whitelaw-22.) 24 BY MR. DAVISON:</p>

<p style="text-align: right;">Page 869</p> <p>1 Q. Sir, I'm handing you what's  2 been marked as Exhibit 22.  3 A. Okay.  4 Q. Have you finished reviewing?  5 A. I have.  6 Q. Sir, do you recall seeing  7 this document?  8 A. Again, I've seen so many  9 documents. I'm going to go to the  10 reliance list and double-check it.  11 Q. Sir, I've looked. I don't  12 think it's in here. But go ahead and  13 double-check my looking.  14 And, sir, if it helps out, I  15 think the Mallinckrodt materials are Page  16 267, 268, and 269.  17 A. I don't see it on the list.  18 Q. Okay. So, sir, the e-mail  19 here reflects discussion over "know your  20 customer's customer." Are you familiar  21 with that term?  22 A. I am familiar with that  23 term.  24 Q. And what do you understand</p>	<p style="text-align: right;">Page 871</p> <p>1 heard anything about know your customer's  2 customer and the regulations do not  3 reflect such a requirement."  4 Did I read that correctly?  5 A. I believe you did read that  6 correctly.  7 Q. So this is the DEA telling  8 Mallinckrodt that there's no regulatory  9 requirement to know their customer's  10 customer, correct?  11 MR. BOGLE: Object to form.  12 Misstates the document.  13 THE WITNESS: No, I actually  14 do not agree with you, because the  15 policy from the DEA comes from  16 corporate headquarters. As best I  17 can tell, without knowing DI  18 Heather White, she is a field  19 investigator.  20 And, therefore, she may have  21 stated this. All I can -- all I  22 can say is that's what the record  23 reflects, is that Ms. Spalding had  24 a conversation with Ms. White and</p>
<p style="text-align: right;">Page 870</p> <p>1 "know your customer's customer" to mean  2 for a pharmaceutical manufacturer?  3 A. It means the pharmaceutical  4 manufacturer should understand who the  5 distributor is in fact selling to. In  6 your case, if we used your general case  7 that you provided earlier, to the  8 pharmacy.  9 Q. Thank you, sir.  10 And one way of looking at  11 that would be through chargeback data; is  12 that fair?  13 A. That is one piece of data  14 that would be useful, yes.  15 Q. Okay. Do you see here that  16 Eileen Spalding states that she had had a  17 conversation with DI Heather White? Do  18 you know who DI Heather White is?  19 A. I can only suppose she is a  20 diversion investigator, but I don't know  21 who she is personally, no.  22 Q. And that, "DI White had  23 stated that she had called NYC and no one  24 there, including Sue Baker, DPM, has</p>	<p style="text-align: right;">Page 872</p> <p>1 Ms. White said -- supposedly said  2 this.  3 But I can't say that that's  4 DEA's policy or -- without more.  5 This is a -- Mallinckrodt's  6 employee's recollection of a  7 conversation with a potential -- I  8 believe diversion investigator.  9 Whether or not it's an accurate  10 representation of the conversation  11 or not, I have no way of knowing.  12 I just know what's on the  13 document.  14 BY MR. DAVISON:  15 Q. Yeah, you haven't seen this  16 document because plaintiffs didn't  17 provide it to you, correct?  18 MR. BOGLE: Object to form.  19 THE WITNESS: I don't recall  20 seeing this document. But I can't  21 tell you why I didn't see the  22 document. I can't go any further  23 than that.  24 BY MR. DAVISON:</p>



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1 Q. All the documents that you  
2 received to review for this case came  
3 from plaintiffs' counsel, correct?  
4 MR. BOGLE: Object to form.  
5 Misstates his prior testimony.  
6 BY MR. DAVISON:  
7 Q. Strike that.  
8 All of the Mallinckrodt  
9 produced documents in this litigation  
10 that you received came from plaintiffs'  
11 counsel, correct?  
12 A. That is correct.  
13 Q. Did Mr. Rafalski tell you  
14 that this was a requirement of the SOM  
15 regulation?  
16 A. Again --  
17 Q. Strike that.  
18 Did Mr. Rafalski tell you  
19 that monitoring chargebacks was a  
20 requirement of the Controlled Substances  
21 Act?  
22 A. Again, I don't rightly  
23 recall our conversation around  
24 chargebacks any more than it's a good

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1 source of information to be used by a  
2 prudent manufacturer to know their  
3 customer's customer. Beyond that general  
4 discussion, I don't recall the specifics.  
5 Q. And sir, you testified  
6 earlier that some of your understanding  
7 that you used in this litigation  
8 regarding the suspicious order monitoring  
9 regulation, Controlled Substances Act,  
10 came from Mr. Rafalski, correct?  
11 MR. BOGLE: Object to form.  
12 THE WITNESS: I testified  
13 that I had conversations with  
14 Mr. Rafalski about the Controlled  
15 Substances Act and regulations and  
16 how DEA operates, yes.  
17 BY MR. DAVISON:  
18 Q. Mr. Rafalski never worked in  
19 DEA headquarters, correct?  
20 A. I honestly don't know his  
21 complete background. So I can't --  
22 without reviewing his background once  
23 more, I can't tell you one way or the  
24 other because I can't remember it in all

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1 that detail.  
2 Q. What was Mr. Rafalski's job  
3 title?  
4 A. As I said to you, I don't  
5 remember it off the top of my head. So  
6 if there's a document you'd like me to  
7 look at, I'll be happy to.  
8 Q. Sir, does it help refresh  
9 your recollection that Mr. Rafalski was a  
10 diversion investigator in the Detroit  
11 field office?  
12 A. Again, I'd like to see  
13 whatever document you're referring to,  
14 Counsel, because if --  
15 Q. If Mr. Rafalski never worked  
16 at DEA headquarters, could Mallinckrodt  
17 have relied on his understanding of the  
18 Controlled Substances Act?  
19 MR. BOGLE: Object to form.  
20 THE WITNESS: Again, I'd  
21 like to know what you mean by  
22 "rely."  
23 BY MR. DAVISON:  
24 Q. Well, I asked you earlier

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1 with respect to Exhibit 22, whether this  
2 was an example of DEA telling  
3 Mallinckrodt that there's no regulatory  
4 requirement to know the customer's  
5 customer.  
6 And I'm paraphrasing. But  
7 one of the statements that you made was  
8 that no, because the policy from DEA  
9 comes from corporate headquarters.  
10 So I -- question, was your  
11 concern that that information was coming  
12 from a field office?  
13 MR. BOGLE: Object to form.  
14 THE WITNESS: Well, first  
15 off, my concern with the document  
16 that you had showed me was it is a  
17 Mallinckrodt employee's  
18 recollection of a conversation  
19 rather than -- rather than any --  
20 of how that conversation  
21 transpired, there's no way to say  
22 whether or not that's an accurate  
23 version of the conversation or  
24 not.

<p style="text-align: right;">Page 877</p> <p>1 So I honestly don't know  2 what DI Heather White actually  3 said, except for the way it's  4 represented on the document.  5 That's my first concern.  6 My second concern would be,  7 again, if you get something, you  8 know, regulatory professionals and  9 compliance professionals know  10 that, again, if you get -- if you  11 hear something from a field office  12 that doesn't comport with what  13 you've heard before, you need to  14 go to the source that makes  15 policy, in this case we are  16 talking DEA headquarters, and  17 inquire further.  18 Hey, am I hearing what's  19 right? Is this the right  20 statement of the policy? Et  21 cetera. Because, again, employees  22 in the field -- and Mallinckrodt  23 has the same experience with sales  24 reps -- sometimes do not state</p>	<p style="text-align: right;">Page 879</p> <p>1 what determines there, correct?  2 A. Headquarters sets policies  3 that if you want to know what the DEA's  4 policy is on a particular topic, you need  5 to hear it from headquarters.  6 Q. Thank you, sir.  7 I'd like to -- so we were  8 talking about chargeback data. And we --  9 we went a little afield. But turning  10 back to chargeback data, sir.  11 In your report do you  12 suggest any metric or method to use in  13 analyzing chargeback data?  14 A. I don't suggest utilizing a  15 specific methodology for analyzing it.  16 What I'm saying is it's a set of data  17 that you -- that a manufacturer should  18 incorporate into their suspicious order  19 monitoring program as appropriate.  20 For example, as you and I  21 just discussed, not everything has a  22 chargeback, so obviously for certain  23 transactions you can't use data that  24 doesn't exist.</p>
<p style="text-align: right;">Page 878</p> <p>1 policy correctly.  2 BY MR. DAVISON:  3 Q. Fair enough, sir.  4 So if there is -- strike  5 that.  6 If the interpretation of the  7 requirements of the Controlled Substances  8 Act for manufacturers differ between  9 Mr. Rafalski, who is at a field office,  10 and members of DEA who are at  11 headquarters, you would say that you  12 listen to the members of DEA that are at  13 headquarters, correct?  14 MR. BOGLE: Object to form.  15 Misstates his testimony.  16 THE WITNESS: Again, I would  17 say you would -- you would inquire  18 from headquarters, this is what  19 I've heard, is this accurate, and  20 get a read from headquarters of  21 whether or not what you're hearing  22 is accurate or not.  23 BY MR. DAVISON:  24 Q. And headquarters' view is</p>	<p style="text-align: right;">Page 880</p> <p>1 What I'm saying is it's up  2 to the manufacturer to incorporate it and  3 they should make an effort to use that  4 data.  5 Q. And, sir, with respect to  6 using that data, it could be used  7 differently by different manufacturers,  8 correct?  9 MR. BOGLE: Object to form.  10 THE WITNESS: Could you --  11 could you restate the question for  12 me, please?  13 BY MR. DAVISON:  14 Q. Sure.  15 Under the -- the  16 Dr. Whitelaw good manufacturers  17 controlled substances compliance  18 program -- or excuse me, anti-diversion  19 compliance program --  20 A. You mean under the  21 attributes that I list in my report that  22 I gleaned from experience in the federal  23 sentencing guidelines and Controlled  24 Substances Act, et cetera? Is that what</p>

<p style="text-align: right;">Page 881</p> <p>1 we're referring to?</p> <p>2 Q. The attributes that are</p> <p>3 listed in your report on Page 36.</p> <p>4 A. Okay. Great.</p> <p>5 Q. You don't define a way that</p> <p>6 you expect manufacturers to monitor</p> <p>7 chargebacks, correct?</p> <p>8 A. No, I do not define a</p> <p>9 specific way for...</p> <p>10 Q. Are you aware of DEA ever</p> <p>11 suggesting a specific metric or method</p> <p>12 that manufacturers are to use in</p> <p>13 analyzing chargeback data?</p> <p>14 MR. BOGLE: Object to form.</p> <p>15 THE WITNESS: No, I am not</p> <p>16 aware of DEA ever suggesting a</p> <p>17 specific methodology to analyze</p> <p>18 and review chargeback data.</p> <p>19 BY MR. DAVISON:</p> <p>20 Q. So under the expectations</p> <p>21 that you have for a manufacturer's</p> <p>22 program, is one way the manufacturer</p> <p>23 could utilize chargeback data to utilize</p> <p>24 the data to look at its distributors and</p>	<p style="text-align: right;">Page 883</p> <p>1 again, you want to talk about the</p> <p>2 bigger picture? That is one part</p> <p>3 of it. But, again, you should</p> <p>4 also then be looking at your</p> <p>5 distributors and asking them some</p> <p>6 serious questions as to, all</p> <p>7 right, if I'm seeing this behavior</p> <p>8 from this pharmacy, and it looks</p> <p>9 to be an outlier, and I am</p> <p>10 concerned about it, could you</p> <p>11 please tell me what you're doing</p> <p>12 about it, because you're my</p> <p>13 distributor.</p> <p>14 BY MR. DAVISON:</p> <p>15 Q. Fair enough.</p> <p>16 So one thing you could do is</p> <p>17 you could restrict the chargebacks, then</p> <p>18 conduct an audit of the distributor,</p> <p>19 correct?</p> <p>20 A. Yes. And at the same time</p> <p>21 request that the distributor stop filling</p> <p>22 orders for that particular pharmacy that</p> <p>23 you are concerned about with your</p> <p>24 product, so that again you're not making</p>
<p style="text-align: right;">Page 882</p> <p>1 where the product is going, and inform</p> <p>2 DEA of that information regarding its</p> <p>3 distributor customers?</p> <p>4 MR. BOGLE: Object to form.</p> <p>5 THE WITNESS: Well, that's</p> <p>6 certainly part of the equation.</p> <p>7 You're missing the last part of</p> <p>8 the equation, which would be, if</p> <p>9 you think you need to inform DEA</p> <p>10 and your product is going in the</p> <p>11 wrong -- going in the wrong</p> <p>12 direction because of chargeback</p> <p>13 data, you should be taking steps</p> <p>14 to make sure that that product</p> <p>15 doesn't -- that product pipeline</p> <p>16 doesn't continue to flow.</p> <p>17 BY MR. DAVISON:</p> <p>18 Q. And would one way of doing</p> <p>19 that be to restrict chargebacks so</p> <p>20 that -- for certain pharmacies that you</p> <p>21 may have questions about?</p> <p>22 MR. BOGLE: Object to form.</p> <p>23 THE WITNESS: Again, it's a</p> <p>24 partial -- partial answer. But</p>	<p style="text-align: right;">Page 884</p> <p>1 the problem worse.</p> <p>2 Q. Fair enough.</p> <p>3 Now, sir, I'd like -- we can</p> <p>4 turn back to 36 just so we're on the same</p> <p>5 page.</p> <p>6 A. Sure.</p> <p>7 Q. All right. So Number 2</p> <p>8 here, we have individual retail pharmacy</p> <p>9 activity. And I think we've discussed</p> <p>10 maybe a little bit about this already</p> <p>11 with respect to chargebacks.</p> <p>12 But -- but my question was,</p> <p>13 you write, "Like the distributor</p> <p>14 thresholds outlined above, the</p> <p>15 manufacturer establishes ordering levels</p> <p>16 for specific pharmacies which if exceeded</p> <p>17 trigger the manufacturer to be concerned</p> <p>18 that the orders are suspicious and that</p> <p>19 action is needed."</p> <p>20 What does that mean, sir?</p> <p>21 A. I'm not sure where you're --</p> <p>22 what it means is for each pharmacy you're</p> <p>23 selling to, you are tracking your product</p> <p>24 going to, you should establish thresholds</p>

<p style="text-align: right;">Page 885</p> <p>1 or some sort of flag of when the ordering  2 pattern, volume, frequency, becomes of  3 concern, that leads you to want to do  4 further inquiry and find out what's going  5 on.  6 Q. All right. So I just want  7 to make sure I understand. You said for  8 each pharmacy you're selling to. Who is  9 the "your" there?  10 A. The manufacturer.  11 Q. Okay. So if the  12 manufacturer is not selling to individual  13 retail pharmacies --  14 A. Through the -- no, I'm  15 talking about --  16 MR. BOGLE: Wait, wait.  17 Wait until --  18 THE WITNESS: Sorry.  19 MR. BOGLE: Wait until he  20 finishes his question.  21 BY MR. DAVISON:  22 Q. So if the manufacturer is  23 not selling to individual retail  24 pharmacies, then this would not apply,</p>	<p style="text-align: right;">Page 887</p> <p>1 trying -- that's what I'm trying  2 to say.  3 BY MR. DAVISON:  4 Q. And how would you track  5 that?  6 A. I'm sorry? Probably  7 starting with chargeback data, but there  8 might be other ways. Again, I wasn't  9 trying to give you an exhaustive list.  10 Q. All right. And so for every  11 pharmacy that buys from any distributor,  12 Mallinckrodt should set a threshold  13 across all distributors, and if it goes  14 above that threshold, then would report  15 it to DEA?  16 A. I didn't say report it to  17 DEA.  18 MR. BOGLE: Object to form.  19 THE WITNESS: I said  20 investigate it further. That  21 could be contacting your  22 wholesaler and asking what's going  23 on. You could be conducting your  24 own investigation, your own audit</p>
<p style="text-align: right;">Page 886</p> <p>1 correct?  2 MR. BOGLE: Object to form.  3 THE WITNESS: I think you're  4 misunderstand -- I probably wasn't  5 clear. What I'm saying is  6 wherever your product is ending up  7 in pharmacy hands, you should have  8 thresholds, especially for this  9 type of product -- we're talking  10 about opioids -- and be looking at  11 their patterns.  12 BY MR. DAVISON:  13 Q. So just so I follow this,  14 even though a manufacturer is not selling  15 to any of these pharmacies, they should  16 set a threshold level of pills purchased  17 from all distributors?  18 MR. BOGLE: Object to form.  19 THE WITNESS: What I'm  20 saying is you should have a  21 threshold of what -- of your  22 product going into that pharmacy,  23 and what you start to get  24 uncomfortable at. That's what I'm</p>	<p style="text-align: right;">Page 888</p> <p>1 of the wholesaler. But again, you  2 should be asking the question why.  3 You need to have something that  4 triggers the question why and you  5 should be asking the question, why  6 is this happening, why am I seeing  7 what I'm seeing, and is it a  8 problem or isn't it.  9 BY MR. DAVISON:  10 Q. Sir, you're aware that  11 manufacturers receive chargebacks after  12 the sales have been made, correct?  13 A. Yes. I'm aware of that  14 fact.  15 Q. You write in, in  16 subsection --  17 A. But it doesn't any --  18 Q. Excuse me, sir. You write  19 in Subsection A --  20 MR. BOGLE: Were you done?  21 BY MR. DAVISON:  22 Q. -- "Where appropriate,  23 information" --  24 A. No, I wasn't.</p>

<p style="text-align: right;">Page 889</p> <p>1 Q. -- "obtained through the  2 manufacturer's sample accountability  3 program is factored into the controlled  4 substance monitoring program."  5 Did I read that correctly?  6 MR. BOGLE: Why don't you  7 let him finish his last answer  8 before you ask that question.  9 MR. DAVISON: No. Special  10 Master Cohen had very clear on an  11 order on this. If you're going to  12 continue to flout it, we can call  13 him on it. But it's my  14 deposition. It's not a trial  15 deposition. It's a discovery  16 deposition. And if he's going to  17 say things that are not responsive  18 to the question --  19 MR. BOGLE: I think he  20 was -- we didn't know what he was  21 going to say. You stopped him  22 from saying anything.  23 Listen, if you want to go  24 on, then let me make a note that</p>	<p style="text-align: right;">Page 891</p> <p>1 it's not less valid just because  2 it's retrospective data. It's  3 still data.  4 MR. DAVISON: Moving -- move  5 to strike everything after "I am  6 aware that chargeback data are  7 received retrospectively, which is  8 what your question was."  9 BY MR. DAVISON:  10 Q. All right. I'd like to turn  11 to Subsection A of Number 2.  12 You write, "Where  13 appropriate information obtained through  14 the manufacturer's sample accountability,  15 e.g., PDMA program, is factored into the  16 controlled substances monitoring  17 program."  18 Sir, did Mallinckrodt  19 provide samples of the controlled  20 substances at issue in this case?  21 A. To my knowledge, no, they  22 did not.  23 Q. All right. And you are only  24 stating that this would be where</p>
<p style="text-align: right;">Page 890</p> <p>1 you are not letting the witness  2 finish his answer.  3 BY MR. DAVISON:  4 Q. Sir, go ahead and finish,  5 and we'll make a note of an inappropriate  6 objection from your counsel.  7 THE WITNESS: That's fine.  8 Can you read back where we were  9 because I've lost track.  10 (Whereupon, the court  11 reporter read back the requested  12 portion of testimony.)  13 THE WITNESS: I am aware  14 that chargeback data are received  15 after -- received retrospectively,  16 which is what your question was,  17 but it doesn't make using it or  18 not using it any less valid.  19 You are talking about a  20 timing issue here. I'm not saying  21 just because it's not realtime  22 data, which is what you are  23 describing, doesn't make its use  24 or rejection of use any less --</p>	<p style="text-align: right;">Page 892</p> <p>1 appropriate, correct?  2 A. That was why it was stated  3 as where appropriate.  4 Q. And so for Mallinckrodt, and  5 with respect to the opioids at issue in  6 this case, it would not be something that  7 would be utilized in a controlled  8 substances --  9 A. I was talking from a bigger  10 picture. If you are dropping  11 noncontrolled samples, obviously you're  12 not dropping controlled samples. You  13 have data that comes out of that system,  14 you should make use of it if it's  15 relevant, if it overlaps a particular  16 prescriber for example, overlaps a  17 particular pharmacy.  18 Again, the whole  19 conversation we're having around is know  20 your customer's customer. And,  21 therefore, using any and all data  22 available to you that you have available  23 to you, to create as fair and accurate a  24 profile of your customer's customer as</p>



<p style="text-align: right;">Page 893</p> <p>1 you can.</p> <p>2 Q. Sir, have you ever seen</p> <p>3 written documentation from the Drug</p> <p>4 Enforcement Agency that state a</p> <p>5 manufacturer has an obligation to know</p> <p>6 its customer customer -- customer's</p> <p>7 customer?</p> <p>8 MR. BOGLE: Object to form.</p> <p>9 THE WITNESS: I'm sorry.</p> <p>10 Can you state that again.</p> <p>11 BY MR. DAVISON:</p> <p>12 Q. Yeah. Have you ever seen</p> <p>13 written documentation from the Drug</p> <p>14 Enforcement Agency that requires a</p> <p>15 manufacturer to know its customer's</p> <p>16 customer?</p> <p>17 MR. BOGLE: Object to form.</p> <p>18 THE WITNESS: I have to go</p> <p>19 back and review my entire report</p> <p>20 from beginning find -- to look to</p> <p>21 answer your question completely.</p> <p>22 We can do that if you'd like.</p> <p>23 BY MR. DAVISON:</p> <p>24 Q. So sitting here today</p>	<p style="text-align: right;">Page 895</p> <p>1 little over an hour. Take a quick</p> <p>2 break.</p> <p>3 MR. DAVISON: Yeah, right</p> <p>4 now is actually a good breaking</p> <p>5 place.</p> <p>6 THE VIDEOGRAPHER: Going off</p> <p>7 the record at 3:30 p.m.</p> <p>8 (Short break.)</p> <p>9 THE VIDEOGRAPHER: Back on</p> <p>10 the record at 3:45 p.m.</p> <p>11 BY MR. DAVISON:</p> <p>12 Q. All right. Dr. Whitelaw,</p> <p>13 I'm on Page 36 and 37 of your report.</p> <p>14 A. I'm still here, yes.</p> <p>15 Q. Great. So I'm on actually,</p> <p>16 37, I should say, so you don't have to</p> <p>17 turn the page.</p> <p>18 A. Okay.</p> <p>19 Q. So we talked a little bit</p> <p>20 about actions that a manufacturer could</p> <p>21 take if they have questions about a</p> <p>22 pharmacy that is purchasing their product</p> <p>23 from a distributor, correct?</p> <p>24 A. That is correct. We did</p>
<p style="text-align: right;">Page 894</p> <p>1 without reviewing your report, you can't</p> <p>2 answer that question. Is that fair?</p> <p>3 MR. BOGLE: Object to form.</p> <p>4 Misstates his testimony.</p> <p>5 THE WITNESS: What I said</p> <p>6 was I'd have to review it to be</p> <p>7 able to find the specific document</p> <p>8 that you're looking for. I don't</p> <p>9 recall a specific document off the</p> <p>10 top of my head.</p> <p>11 BY MR. DAVISON:</p> <p>12 Q. Well, do you recall</p> <p>13 generally that DEA guidance exists that a</p> <p>14 manufacturer is required to review its</p> <p>15 customer's customer?</p> <p>16 A. Again, I would want to</p> <p>17 review my report.</p> <p>18 Q. So you don't have a</p> <p>19 recollection of that sitting here today?</p> <p>20 A. I can't recall off the top</p> <p>21 of my head.</p> <p>22 Q. Thank you, sir.</p> <p>23 MR. BOGLE: When you reach a</p> <p>24 good stopping point, we're a</p>	<p style="text-align: right;">Page 896</p> <p>1 have that conversation.</p> <p>2 Q. And would those be the</p> <p>3 actions that you'd expect -- so you'd</p> <p>4 expect certain actions under Number 3 of</p> <p>5 your expectations labeled "Taking</p> <p>6 Action"? Is that what you're referring</p> <p>7 to?</p> <p>8 A. Yeah, that's what I'm</p> <p>9 referring to. Yes.</p> <p>10 Q. You -- excuse me.</p> <p>11 You write, "The manufacturer</p> <p>12 notifies and provides details of the</p> <p>13 suspicious activity to both the DEA and</p> <p>14 the distributor," correct?</p> <p>15 A. That's what I'm suggesting,</p> <p>16 yes.</p> <p>17 Q. So that could be in a</p> <p>18 letter -- letter that the manufacturer</p> <p>19 sends to a distributor, the DEA at the</p> <p>20 same time, saying we have some concerns</p> <p>21 about this pharmacy, correct?</p> <p>22 A. I would say that would be --</p> <p>23 certainly be one method of doing it, yes.</p> <p>24 Q. All right. "The</p>

<p style="text-align: right;">Page 897</p> <p>1 manufacturer demands the distributor, and 2 any secondary distributor if known, 3 follow up and take appropriate action 4 regarding the highlighted pharmacies." 5 That's letter B of your 6 "Taking Action," correct? 7 A. That is correct. 8 Q. And one way of doing that 9 would be to request the due diligence 10 files from the distributor so the 11 manufacturer can look at what the 12 distributor knows about the pharmacy, 13 correct? 14 A. That's one method. Not the 15 only method. But certainly an -- a 16 method. 17 Q. And, "The manufacturer 18 maintains contact with the distributor 19 and any secondary distributor if known, 20 requiring them to provide details on the 21 outcome of any investigations including 22 actions taken by the distributors against 23 the pharmacies." 24 And this could be included</p>	<p style="text-align: right;">Page 899</p> <p>1 anti-diversion programs," correct? 2 A. Yes. 3 Q. Are you aware that 4 Mallinckrodt conducted audits of its 5 distributor customers? 6 MR. BOGLE: Objection as to 7 time. Form as to time. 8 THE WITNESS: Can you be 9 more specific for me, please? 10 BY MR. DAVISON: 11 Q. Well, my question is -- is 12 general now. So all the time of your 13 review period, which I think was 1996 to 14 2018. 15 A. I'd have to go back and look 16 at my report to be absolutely certain. 17 So give me a minute. 18 Q. So I just want to -- the 19 question is yes or no. Are you aware 20 whether Mallinckrodt did audits of 21 distributors during your review period? 22 MR. BOGLE: Object to form. 23 THE WITNESS: And again, 24 I -- to be precise in my answer to</p>
<p style="text-align: right;">Page 898</p> <p>1 through an audit or a follow-up 2 conversation with the distributor, 3 correct? 4 A. Either, you could do either. 5 My suggestion would be that you would 6 probably want to have follow-up 7 conversation with the distributor. 8 Because if you're doing an audit on a 9 annual basis, which it tends to be 10 usually an annual audit cycle, a year is 11 an awful long time to wait to follow up 12 to make sure that this hasn't fallen into 13 the black hole. 14 So that's really what we are 15 talking about here, is you provide the 16 information to the distributor and the 17 distributor doesn't do anything to it. 18 And nobody bothers to follow up till a 19 year or more has passed. So that was 20 the... 21 Q. Looking at Number 4 of your 22 expectations, lists audits. "The 23 manufacturer conducts both routine and 24 for-cause audits of these distributors</p>	<p style="text-align: right;">Page 900</p> <p>1 you, I would need to consult my 2 report. So if you're going to let 3 me consult my report, I can give 4 you an answer. Otherwise... 5 BY MR. DAVISON: 6 Q. Sir, do you plan to bring 7 your report with you to trial? 8 A. I would plan to have it 9 available, if needed. Why? 10 Q. So do you plan to review it 11 when you're on the jury stand? 12 A. I honestly hadn't thought 13 that far ahead if you want to -- to be 14 honest. 15 Q. So you may sit there in 16 front of a jury with your report in front 17 of you, to look back on as you're 18 answering questions from plaintiffs 19 during the trial? 20 MR. BOGLE: Object to form. 21 THE WITNESS: Again, we're 22 here -- we're here at a 23 deposition. We haven't gotten to 24 that level of discussion. So I'm</p>

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1 going to say to you, I don't know.  
2 BY MR. DAVISON:  
3 Q. Sir, out of the -- let me  
4 ask a question because I've forgotten the  
5 number.  
6 How many hours have you  
7 spent on your report in preparation for  
8 this case?  
9 A. Around 1200.  
10 Q. Okay. That's what I  
11 thought, but I wasn't certain so I didn't  
12 want to get it wrong.  
13 How many of those 1200 hours  
14 were spent in your review of  
15 Mallinckrodt?  
16 A. I would have to go look at  
17 precisely. But it -- for each one,  
18 each -- in general, each company I looked  
19 at took about a month's worth of work.  
20 Q. So you spent about a month's  
21 worth of work on Mallinckrodt and you  
22 can't recall without going back into your  
23 report whether Mallinckrodt ever  
24 conducted an audit of one of its

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1 distributor customers?  
2 MR. BOGLE: Object to form.  
3 THE WITNESS: What I'm  
4 saying, sir, is I would want to  
5 consult my reports so that I give  
6 you an accurate answer. That's  
7 what I've been saying to you all  
8 along.  
9 BY MR. DAVISON:  
10 Q. All right. So the answer is  
11 you can't tell me the answer without  
12 looking at your report?  
13 MR. BOGLE: Object to form.  
14 THE WITNESS: Did he say  
15 anything?  
16 MR. BOGLE: You can answer.  
17 THE WITNESS: I'm not sure  
18 there was a question, but...  
19 BY MR. DAVISON:  
20 Q. So the answer is that you  
21 cannot tell me yes or no whether  
22 Mallinckrodt has done an audit of a  
23 distributor customer without reviewing  
24 your report?

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1 MR. BOGLE: Object to form.  
2 THE WITNESS: What -- what  
3 I'm telling you is I would like to  
4 review my report before I answer  
5 your question.  
6 BY MR. DAVISON:  
7 Q. So, sir, that's not an  
8 answer to my question.  
9 My question is yes or no,  
10 can you tell me?  
11 MR. BOGLE: Object to form.  
12 THE WITNESS: I can't recall  
13 off the top of my head without  
14 reviewing my report.  
15 BY MR. DAVISON:  
16 Q. That's exactly the answer  
17 that I was asking a question about, sir,  
18 thank you.  
19 All right. Sir, if you can  
20 turn to Page 42 of your report.  
21 A. Yes.  
22 Q. In Section 6.7, it says,  
23 "Manufacturer - Prescriber Relationship,"  
24 right?

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1 A. It does.  
2 Q. And you state that "a  
3 manufacturer should instruct and require  
4 its sales representatives and inhouse  
5 field support and marketing personnel to  
6 provide any observations of potential  
7 diversionary behavior to their inhouse  
8 compliance department for further  
9 evaluation and potential action,"  
10 correct?  
11 A. That is correct.  
12 Q. And, sir, is -- is this  
13 something that's explicitly laid out in  
14 the CSA?  
15 A. It is embedded in the CSA.  
16 Q. And it's embedded under  
17 those -- those four words of controls  
18 against effective diversion, correct?  
19 MR. BOGLE: Object to form.  
20 THE WITNESS: Yes, as well  
21 as under the federal sentencing  
22 guidelines of what an effective  
23 compliance program looks like as  
24 well, so...

<p style="text-align: right;">Page 905</p> <p>1 MR. DAVISON: Move to strike  2 as nonresponsive "as well as under  3 the federal sentencing guidelines  4 of what an effective compliance  5 program looks like as well."  6 BY MR. DAVISON:  7 Q. And, sir, there's nothing in  8 the suspicious order monitoring  9 regulation that requires sales reps to be  10 involved in monitoring physicians,  11 correct?  12 MR. BOGLE: Object to form.  13 THE WITNESS: Could you  14 state the question again for me,  15 please?  16 BY MR. DAVISON:  17 Q. There's nothing in the  18 suspicious order monitoring regulation  19 that requires sales reps to be involved  20 in monitoring physician behavior,  21 correct?  22 MR. BOGLE: Object to form.  23 THE WITNESS: There is no  24 specific wording in the</p>	<p style="text-align: right;">Page 907</p> <p>1 excuse me -- strike that.  2 You're not claiming that a  3 generic manufacturer has an obligation to  4 monitor physicians through a sales force,  5 correct?  6 MR. BOGLE: Object to form.  7 THE WITNESS: I think you're  8 missing the whole point of this  9 section, which is basically, if  10 you have a sales force and the  11 sales force calls on the  12 physician, and they observe bad  13 behavior, troubling behavior is  14 perhaps a better term, that  15 information should be taken back  16 to headquarters and reported to  17 the compliance department. You  18 just don't ignore it and pretend  19 it's not happening. That's what  20 I'm talking about.  21 BY MR. DAVISON:  22 Q. And so within that statement  23 is, if you don't have a sales force, you  24 don't have an obligation to create one to</p>
<p style="text-align: right;">Page 906</p> <p>1 regulation.  2 BY MR. DAVISON:  3 Q. Thank you.  4 Sir, you understand the  5 differences between generic  6 pharmaceutical products and branded  7 pharmaceutical products?  8 A. I do.  9 Q. All right. And you  10 understand that generics products are --  11 are not promoted by a field sales force  12 that interacts with physicians, correct?  13 A. In general, no, they are  14 not.  15 Q. Okay. And, sir,  16 Mallinckrodt did not promote its generic  17 products with a field sales force that  18 interacted directly with the physicians,  19 correct?  20 A. I did not see anything to  21 that effect.  22 Q. And so you're not claiming  23 that there is an obligation of a generic  24 manufacturer to somehow promote its --</p>	<p style="text-align: right;">Page 908</p> <p>1 somehow monitor physicians, correct?  2 A. I'm not saying that you have  3 to create a sales force. I'm saying  4 again the whole gist of this is you have  5 available information, if you have boots  6 on the ground, if you have people out  7 there who are observing behavior and they  8 see something that's troubling, you know,  9 it's about as basic as what you see on  10 Amtrak these days. If you see something,  11 say something.  12 Q. And all of that -- that  13 obligation, again, comes from the four  14 words "effective controls against  15 diversion," right?  16 A. It comes from the federal  17 sentencing guidelines together with the  18 four words of "effective controls against  19 diversion," yes.  20 Q. You also mention IMS data,  21 correct?  22 A. Is there a particular  23 section that you're looking at?  24 Q. Yeah. Page 43. At the top.</p>

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1 "Upon receipt of this information, the  
2 compliance department or other  
3 experienced investigators should conduct  
4 an appropriate investigation to determine  
5 the validity of the information using all  
6 available sources of information, e.g.,  
7 the internet, IMS data, et cetera."  
8 A. Yes. I see what I said.  
9 Q. All right. You're aware  
10 that not all manufacturers purchase IMS  
11 data, correct?  
12 A. I am aware of that fact.  
13 Q. And you're not stating that  
14 there's a requirement under the CSA for a  
15 manufacturer to purchase IMS data, right?  
16 MR. BOGLE: Object to form.  
17 THE WITNESS: Again, I think  
18 we're missing the point of what  
19 I'm conveying. If IMS data is  
20 available, it should be used.  
21 If you have data inhouse  
22 that you have access to that's  
23 pertinent to keeping, you know, to  
24 keeping an eye out for suspicious

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1 behavior, you should be using that  
2 data.  
3 BY MR. DAVISON:  
4 Q. And sir, I understand that,  
5 I just want to be clear, I don't think  
6 I'm missing the point. I'm asking you  
7 specific questions about whether or not  
8 things have to use it. The reason I'm  
9 doing that is because we need to have an  
10 understanding of what your opinions are.  
11 So I understand what you  
12 said, but if you could answer my  
13 question.  
14 A manufacturer is not  
15 required by the CSA to purchase IMS data,  
16 correct?  
17 MR. BOGLE: Object to form.  
18 THE WITNESS: The words  
19 "purchase IMS data" are not in the  
20 CSA requirements, no.  
21 BY MR. DAVISON:  
22 Q. And even under your opinion,  
23 you're not saying that they are required  
24 to do that, whether the words are in the

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1 CSA or not?  
2 MR. BOGLE: Object to form.  
3 THE WITNESS: What I'm  
4 saying, obviously, if the words  
5 were in the CSA that would be a  
6 different story, but since they  
7 are not, what we're talking  
8 about -- no, I'm not saying that  
9 you have to go out and buy it.  
10 I'm saying if you have it inhouse,  
11 you ought to be using it.  
12 MR. DAVISON: Can we go off  
13 the record for just a second. My  
14 battery is almost dead on this.  
15 THE VIDEOGRAPHER: Going off  
16 the record 3:57 p.m.  
17 (Brief pause.)  
18 THE VIDEOGRAPHER: Back on  
19 the record at 3:57 p.m.  
20 BY MR. DAVISON:  
21 Q. All right, sir. We've  
22 talked about the general expectations.  
23 I'd now like to turn to your review  
24 specifically of Mallinckrodt. And just

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1 to help you out with that. It starts on  
2 Page 208. But I wanted to start by  
3 asking about your evaluation. If you can  
4 turn to Page 43. Sorry.  
5 A. Okay.  
6 Q. All right. So at the bottom  
7 of the page, you write, "For each company  
8 the analysis focuses on answering two  
9 questions. The first question is whether  
10 objective evidence exists supporting that  
11 the company being reviewed worked to  
12 establish a suspicious order monitoring  
13 system as well as controlled substances  
14 and corporate compliance programs."  
15 Did I review that correctly?  
16 Excuse me. Did I read that correctly?  
17 A. Yes.  
18 Q. Sir, did you find objective  
19 evidence that Mallinckrodt worked to  
20 establish a suspicious order monitoring  
21 system as well as controlled substances  
22 and corporate compliance programs?  
23 MR. BOGLE: Object to form.  
24 THE WITNESS: Yes, I did.



<p style="text-align: right;">Page 913</p> <p>1 BY MR. DAVISON:</p> <p>2 Q. Thank you. And so the</p> <p>3 second question is, "Whether there is</p> <p>4 objective evidence showing that the</p> <p>5 company met its three-prong program</p> <p>6 effectiveness requirement by: A, having</p> <p>7 a program that prevents and detects</p> <p>8 criminal conduct by an organization's</p> <p>9 employees; and B, maintaining effective</p> <p>10 controls against diversion; including, C,</p> <p>11 maintaining and operating an effective</p> <p>12 system to identify, hold, investigate,</p> <p>13 and report suspicious orders of</p> <p>14 controlled substances."</p> <p>15 Did I read that correctly?</p> <p>16 A. Yes.</p> <p>17 Q. So with respect to the</p> <p>18 Mallinckrodt section of your report, was</p> <p>19 your focus on answering that second</p> <p>20 question?</p> <p>21 MR. BOGLE: Object to form.</p> <p>22 Overbroad.</p> <p>23 THE WITNESS: Well, my focus</p> <p>24 was answering both questions, but</p>	<p style="text-align: right;">Page 915</p> <p>1 in this report.</p> <p>2 Q. And that's because</p> <p>3 compliance programs have to be looked at</p> <p>4 in the totality, correct?</p> <p>5 A. I believe so, yes.</p> <p>6 Q. And I believe you testified</p> <p>7 earlier that you had requested certain</p> <p>8 categories of documents from plaintiffs</p> <p>9 and that those categories were based on</p> <p>10 the seven, now eight federal sentencing</p> <p>11 guidelines; is that correct?</p> <p>12 A. Yes. That's the framework I</p> <p>13 was using, yes.</p> <p>14 Q. And -- and you also stated</p> <p>15 that you requested transcripts from the</p> <p>16 plaintiffs' attorneys, correct?</p> <p>17 A. You mean deposition</p> <p>18 transcripts?</p> <p>19 Q. Absolutely. Deposition</p> <p>20 transcripts.</p> <p>21 A. Yes, I requested deposition</p> <p>22 transcripts.</p> <p>23 Q. Okay. And when you</p> <p>24 requested transcripts, did you request</p>
<p style="text-align: right;">Page 914</p> <p>1 we obviously had enough evidence</p> <p>2 that I reviewed to get past the</p> <p>3 first level. So yes, it was on</p> <p>4 the second -- the details are on</p> <p>5 the second part, yes.</p> <p>6 BY MR. DAVISON:</p> <p>7 Q. Thank you. You can turn to</p> <p>8 Page 208.</p> <p>9 Sir, in your evaluation of</p> <p>10 Mallinckrodt's suspicious order</p> <p>11 monitoring -- excuse me. Strike that.</p> <p>12 In your evaluation of</p> <p>13 Mallinckrodt's anti-diversion compliance</p> <p>14 program, you used the same methodology</p> <p>15 that we discussed earlier, correct?</p> <p>16 A. Yes, sir.</p> <p>17 Q. So you reviewed the standard</p> <p>18 operating procedures?</p> <p>19 A. I reviewed a whole host of</p> <p>20 information I asked for. I applied my</p> <p>21 expertise and experience, looked at those</p> <p>22 documents, conversations. It's the</p> <p>23 same -- it's the same methodology that I</p> <p>24 applied to every other company reviewed</p>	<p style="text-align: right;">Page 916</p> <p>1 categories of transcripts?</p> <p>2 MR. BOGLE: Object to form.</p> <p>3 THE WITNESS: I requested</p> <p>4 people's transcripts. I'm not</p> <p>5 sure -- I'm not sure I'm following</p> <p>6 you yet.</p> <p>7 BY MR. DAVISON:</p> <p>8 Q. Well, how did you determine</p> <p>9 which people to request a transcript for?</p> <p>10 A. I utilized the</p> <p>11 organizational charts that I had seen,</p> <p>12 had -- had conversations with counsel,</p> <p>13 who were -- who was likely to have the</p> <p>14 most responsive information based on the</p> <p>15 depositions that have been taken in the</p> <p>16 categories I was looking in. It was a</p> <p>17 whole series of -- it was an iterative</p> <p>18 process.</p> <p>19 Q. All right. And so you</p> <p>20 stated that you utilized the</p> <p>21 organizational charts --</p> <p>22 A. When I had them.</p> <p>23 Q. Excuse me. The part -- you</p> <p>24 utilized them as one of other ways of --</p>

<p style="text-align: right;">Page 917</p> <p>1 of reviewing them, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And did you request</p> <p>4 transcripts for example, for each</p> <p>5 employee that was a member of a certain</p> <p>6 category?</p> <p>7 A. I'm not sure I'm</p> <p>8 following -- you've lost me.</p> <p>9 Q. Fair enough.</p> <p>10 Sir, you reviewed</p> <p>11 transcripts of Mallinckrodt's national</p> <p>12 account managers; is that correct?</p> <p>13 A. Yes. I reviewed</p> <p>14 transcripts.</p> <p>15 Q. Did you request from</p> <p>16 plaintiffs' counsel that they provide you</p> <p>17 transcripts of every national account</p> <p>18 manager for which a deposition was taken?</p> <p>19 A. I honestly don't recall</p> <p>20 whether I asked for all or some. I can't</p> <p>21 tell you at this point.</p> <p>22 Q. Would it be your standard</p> <p>23 practice to -- to interview every</p> <p>24 employee within a certain title?</p>	<p style="text-align: right;">Page 919</p> <p>1 account managers or only a couple?</p> <p>2 A. I honestly do not recall.</p> <p>3 Q. Do you remember whether you</p> <p>4 asked for testimony of national account</p> <p>5 managers at all?</p> <p>6 A. I did ask for depositions</p> <p>7 from national account managers.</p> <p>8 Q. And did you request specific</p> <p>9 people?</p> <p>10 A. As I said, I don't recall</p> <p>11 this precise request. I do know I</p> <p>12 requested national account manager</p> <p>13 depositions.</p> <p>14 Q. Did you request deposition</p> <p>15 transcripts of sales reps?</p> <p>16 A. I don't recall a specific</p> <p>17 request for those.</p> <p>18 Q. Did you request deposition</p> <p>19 transcripts for Mallinckrodt's head of</p> <p>20 sales?</p> <p>21 A. Again, I don't recall a</p> <p>22 specific request for that deposition.</p> <p>23 Q. Sir, did you request the</p> <p>24 deposition transcript of Mallinckrodt's</p>
<p style="text-align: right;">Page 918</p> <p>1 MR. BOGLE: Object to form.</p> <p>2 MR. DAVISON: Strike that,</p> <p>3 that was a bad question.</p> <p>4 BY MR. DAVISON:</p> <p>5 Q. Under your methodology that</p> <p>6 we had discussed earlier --</p> <p>7 A. Yes.</p> <p>8 Q. -- would your expectation be</p> <p>9 that you would interview multiple</p> <p>10 employees with the same position?</p> <p>11 MR. BOGLE: Object to form.</p> <p>12 THE WITNESS: Again,</p> <p>13 within -- I would interview those</p> <p>14 employees I needed or felt were</p> <p>15 necessary to form my opinion.</p> <p>16 I don't have a set number.</p> <p>17 If you're looking for a set</p> <p>18 number, I don't have that. I</p> <p>19 don't -- I don't use a set number.</p> <p>20 BY MR. DAVISON:</p> <p>21 Q. And you don't recall, with</p> <p>22 respect to Mallinckrodt, whether you</p> <p>23 requested from plaintiffs all of the</p> <p>24 deposition transcripts of national</p>	<p style="text-align: right;">Page 920</p> <p>1 manager of controlled substance</p> <p>2 compliance?</p> <p>3 A. Can you be more specific on</p> <p>4 period of time, because again I know</p> <p>5 people's titles change. Yes, I would</p> <p>6 have requested the key controlled</p> <p>7 substances personnel. So can you -- I</p> <p>8 need you to be more specific.</p> <p>9 Q. Sure. Did you request</p> <p>10 deposition transcripts from</p> <p>11 Mallinckrodt's current manager of</p> <p>12 controlled substance compliance?</p> <p>13 MR. BOGLE: Object to form.</p> <p>14 THE WITNESS: Again, I would</p> <p>15 have asked for transcripts from</p> <p>16 the key people responsible for</p> <p>17 controlled substance compliance</p> <p>18 review. And again, if you're</p> <p>19 asking me about a specific name --</p> <p>20 BY MR. DAVISON:</p> <p>21 Q. Well, based on a -- on a job</p> <p>22 title, sir, would a manager of controlled</p> <p>23 substance compliance be someone that</p> <p>24 would be important to review in</p>

<p>Page 921</p> <p>1 evaluating a manufacturer's controlled 2 substance compliance program? 3 MR. BOGLE: Object to form. 4 THE WITNESS: There is a 5 potential, but there's also the 6 potential that you are looking for 7 the if. You're saying -- are they 8 the head of the programs? Are 9 they the ones ultimately 10 responsible? Are they the highest 11 authority responsible? Do they 12 have day-to-day operational 13 oversight? 14 There are a number of 15 factors in selecting whether or 16 not you talk to certain people. 17 BY MR. DAVISON: 18 Q. Well, sir, you -- you would 19 agree with me that to do an effective 20 internal investigation, you can't just 21 talk to the highest people up there, 22 right? 23 MR. BOGLE: Object to form. 24 THE WITNESS: I think it</p> <p>Page 922</p> <p>1 depends on the kind of 2 investigation you're doing and 3 what you're investigating. 4 BY MR. DAVISON: 5 Q. Well, with -- with your 6 investigation for this litigation of 7 Mallinckrodt, would it have been 8 sufficient for you to just talk to the 9 highest people at Mallinckrodt? 10 MR. BOGLE: Object to form. 11 THE WITNESS: Well, you're 12 making it sound like all I did was 13 look at -- again, if that was all 14 you did was -- was depositions in 15 a -- in a vacuum, no, it would not 16 be. 17 But again there's a whole 18 lot of other documents and 19 information that went into this 20 review. 21 BY MR. DAVISON: 22 Q. Sir, did you request from 23 plaintiffs that they provide you with 24 testimony -- excuse me -- deposition</p>	<p>Page 923</p> <p>1 transcripts of any testimony taken for 2 people in Mallinckrodt's controlled 3 substance compliance department? 4 MR. BOGLE: Object to form. 5 THE WITNESS: To the best of 6 my recollection, I did. 7 BY MR. DAVISON: 8 Q. Sir, do you know who Eileen 9 Spalding is? 10 A. I know the name. 11 Q. I'll represent to you that 12 she is Mallinckrodt's current manager of 13 controlled substance compliance. Do you 14 recall reviewing her testimony? 15 A. I honestly don't recall her 16 deposition. But I can go -- again, let's 17 look at the reliance list. It will tell 18 you whose depositions -- 19 Q. No problem, sir, that's on 20 Page 2 -- 277. 21 A. I do not see her deposition. 22 Q. Plaintiffs didn't give you 23 Eileen Spalding's deposition transcript, 24 correct?</p> <p>Page 924</p> <p>1 A. What I said was, I don't 2 recall reviewing Eileen Spalding's 3 deposition transcript. 4 Q. Well, if you had reviewed 5 it, it would be right here in -- in your 6 report, right, sir? 7 A. Unless it was mistakenly 8 left off, yes, it should be there. 9 Q. All right. And did you 10 review all the transcripts that 11 plaintiffs provided you? 12 A. Again, I don't remember all 13 the transcripts that I have. I've seen 14 so many transcripts. So I -- I can't 15 answer that question. 16 Q. I think my question is a 17 little bit different. I'm not asking if 18 you remember all -- all the transcripts 19 you have. 20 I'm asking if you reviewed 21 all the transcripts that plaintiffs 22 provided you. 23 A. Well, since the only 24 transcripts I reviewed would have come</p>
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1 from my requests of plaintiffs' counsel,  
2 again I don't -- don't know all of the  
3 list I have. But again, everything  
4 that's on my list here, I did review.  
5 Q. And was it your practice in  
6 the -- the 1200 hours that you spent, to  
7 review all of the transcripts that  
8 plaintiffs' counsel provided you?  
9 A. Again, if I had it, I would  
10 have looked at it.  
11 Q. Thank you, sir.  
12 Sir, are you offering an  
13 opinion as to the effectiveness of  
14 Mallinckrodt's current controlled  
15 substances compliance program?  
16 A. I am offering an opinion  
17 based on Mallinckrodt's controlled  
18 substances compliance program for the  
19 period that's in my report.  
20 Q. All right. So not one for  
21 today, correct?  
22 MR. BOGLE: Object to form.  
23 THE WITNESS: I'm sorry?  
24 BY MR. DAVISON:

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1 Q. You are not offering an  
2 opinion as to Mallinckrodt's current  
3 controlled substances compliance program?  
4 A. I'm offering it for the time  
5 frame that's set out in my report.  
6 Q. And the time frame set out  
7 in your report is 1996 to 2018; is that  
8 correct?  
9 A. That is correct.  
10 Q. So you're offering an  
11 opinion on Mallinckrodt's controlled  
12 substances compliance program in 2018,  
13 correct?  
14 A. Correct.  
15 Q. 2017?  
16 A. Yes.  
17 Q. We can go all the way back  
18 to 1996?  
19 A. We can.  
20 Q. So you're offering an  
21 opinion for every single year of  
22 Mallinckrodt's controlled substance  
23 compliance program 1996 to 2018?  
24 A. I am offering an opinion

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1 about the effectiveness of the program  
2 for that period of time.  
3 Q. Sir, sitting here today, can  
4 you think of a single document that you  
5 reviewed regarding Mallinckrodt's  
6 controlled substance compliance program  
7 that was later than 2012?  
8 A. Again, I don't recall. I'd  
9 have to go look at all the documents and  
10 all the dates, sir.  
11 Q. Fair enough.  
12 (Document marked for  
13 identification as Exhibit  
14 Whitelaw-23.)  
15 BY MR. DAVISON:  
16 Q. I'm going to mark  
17 Exhibit 23, which is a chart that may  
18 help us a little bit. We put this  
19 together. This isn't anything that  
20 Mallinckrodt has produced.  
21 But, sir, I know you  
22 reviewed a number of documents. You  
23 reviewed about 150 out of the 1.6 million  
24 that Mallinckrodt produced. So we

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1 thought it would be helpful to put  
2 together a chart to show you what year  
3 those documents came from.  
4 A. Okay.  
5 Q. So go ahead and take a look  
6 at this chart. Do you need any time?  
7 A. I can see the chart.  
8 Q. All right. So, sir, if you  
9 look at the chart, it appears that you  
10 reviewed four documents from 2018,  
11 correct?  
12 MR. BOGLE: Does this  
13 include deposition exhibits?  
14 MR. DAVISON: This includes  
15 the documents that are listed on  
16 his relied upon document.  
17 MR. BOGLE: So it does  
18 include deposition exhibits?  
19 MR. DAVISON: I'm not sure  
20 if it does include deposition  
21 exhibits. I'm not going to  
22 represent that it does.  
23 MR. BOGLE: Okay.  
24 THE WITNESS: So I see that

<p style="text-align: right;">Page 929</p> <p>1 your chart says four, yes. 2 BY MR. DAVISON: 3 Q. Okay. Sir, in looking at 4 this chart, from 2013 to 2018, you 5 reviewed a total of 11 documents, 6 correct? 7 A. Those are the numbers that 8 you have, yes. 9 Q. Well, sitting here today do 10 you have any reason to doubt those 11 numbers? 12 MR. BOGLE: Object to form. 13 THE WITNESS: I think you 14 just raised one question. You 15 don't know whether it includes 16 deposition exhibits or not. So 17 I'm just going by the numbers that 18 are on your page. 19 BY MR. DAVISON: 20 Q. All right. Well, sir, can 21 you recall a single document that you 22 actually put a citation to in your report 23 from Mallinckrodt's SOM program post 24 2012?</p>	<p style="text-align: right;">Page 931</p> <p>1 your statement that Mallinckrodt's 2 controlled substances compliance program 3 was not effective in 2016? 4 A. I'd have to go back and 5 review my report to be able to give you 6 an answer to that question. 7 Q. So you can't recall sitting 8 here today without going through your 9 report any basis for a claim that 10 Mallinckrodt's suspicious order 11 monitoring program was not effective in 12 2016? 13 A. I can't tell you without 14 reviewing my report in detail. 15 Q. Are you aware that 16 Mr. Rafalski said that he had no opinion 17 as to the effectiveness of Mallinckrodt's 18 suspicious order monitoring program post 19 2011? 20 A. I am not aware of what 21 Mr. Rafalski said about Mallinckrodt at 22 all. 23 Q. And, sir, if the only 24 documents you reviewed from 2000 -- from</p>
<p style="text-align: right;">Page 930</p> <p>1 A. Considering I have several 2 thousand footnotes, no, not off the top 3 of my head right here. 4 Q. Well, sir, if all of your 5 citations are prior to 2012, those are 6 the documents that you thought were most 7 important, right? 8 MR. BOGLE: Object to form. 9 THE WITNESS: Again, as I 10 said to you, you asked me if I 11 could recall. I told you I've got 12 thousands of footnotes. I can't 13 recall. 14 BY MR. DAVISON: 15 Q. Sir, what's the basis for 16 your statement that Mallinckrodt's 17 controlled substances compliance program 18 was not effective in 2016? 19 MR. BOGLE: Object to form. 20 THE WITNESS: Could you 21 restate the question for me, 22 please? 23 BY MR. DAVISON: 24 Q. Sir, what is the basis for</p>	<p style="text-align: right;">Page 932</p> <p>1 post 2012 relating to Mallinckrodt's 2 controlled substances compliance program 3 were standard operating procedures, you'd 4 agree with me that that is not sufficient 5 for you to make a determination as to the 6 effectiveness of Mallinckrodt's 7 controlled substance compliance program, 8 right? 9 MR. BOGLE: Object to form. 10 THE WITNESS: Do you want to 11 restate the question? 12 MR. DAVISON: Can we read it 13 back? 14 (Whereupon, the court 15 reporter read back the requested 16 portion of testimony.) 17 THE WITNESS: If that was 18 the only documents that I 19 reviewed, I'm not sure how -- I'm 20 not sure what I can tell you on 21 that. 22 BY MR. DAVISON: 23 Q. Well, I think we agreed 24 earlier that looking at SOPs alone is not</p>



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1 consistent with your methodology for  
2 evaluating the controlled substance  
3 compliance program, correct?  
4 A. Not a complete holistic  
5 program, no. But you're assuming that  
6 that's the only -- those are the only  
7 documents that I looked at. Don't forget  
8 that I looked at depositions, et cetera,  
9 so...  
10 Q. So I think your answer then,  
11 if -- again, a hypothetical -- the only  
12 documents that you looked at that were  
13 post 2012 were standard operating  
14 procedures, that would not be sufficient  
15 for you to draw a conclusion as to the  
16 effectiveness of Mallinckrodt's  
17 controlled substance compliance program?  
18 MR. BOGLE: Object to form.  
19 THE WITNESS: Can you say it  
20 again?  
21 Brandon, can we take a  
22 break? I need -- I need --  
23 BY MR. DAVISON:  
24 Q. There's a question pending.

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1 MR. BOGLE: You can answer  
2 the question and then we'll take a  
3 break.  
4 MR. DAVISON: Yeah, that's  
5 fine.  
6 THE WITNESS: I need to go  
7 to the bathroom, actually.  
8 BY MR. DAVISON:  
9 Q. I just want an answer to my  
10 question, and then we'll take a break.  
11 A. Sure.  
12 Q. So this is a hypothetical.  
13 If the only documents that you looked at,  
14 that were post 2012, that would not be  
15 sufficient for you to draw a conclusion  
16 as to the effectiveness of  
17 Mallinckrodt's -- I'm going to strike  
18 that and start over because reading it --  
19 THE COURT REPORTER: You can  
20 stop it. You can stop the  
21 movement.  
22 BY MR. DAVISON:  
23 Q. Sir, if the only documents,  
24 if the only Mallinckrodt documents that

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1 you looked at post 2012 were standard  
2 operating procedures, you would agree  
3 with me that under your methodology, that  
4 is not sufficient for you to draw a  
5 conclusion as to the effectiveness of  
6 Mallinckrodt's controlled substance  
7 compliance program?  
8 MR. BOGLE: Object to form.  
9 THE WITNESS: I would say it  
10 would be -- if that were the case,  
11 I would say, it would be  
12 sufficient to at least note that  
13 there's a deficiency in the  
14 program around written standards.  
15 BY MR. DAVISON:  
16 Q. And, sir, just one more  
17 question. If you didn't write in your  
18 report specific deficiencies relating to  
19 standard operating procedures, are you  
20 intending to offer an opinion as with  
21 respect to those deficiencies?  
22 A. I am not at this point  
23 expecting to amend this report unless  
24 there's new and available information for

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1 me to work with.  
2 Q. So sitting here today the  
3 answer to that question is no?  
4 MR. BOGLE: You can answer  
5 that, and then we're taking a  
6 break.  
7 MR. DAVISON: Yeah.  
8 THE WITNESS: As I said,  
9 unless there's new available  
10 information I need to consider, I  
11 am not -- at this current point I  
12 have no intention of amending the  
13 report.  
14 MR. BOGLE: All right.  
15 MR. DAVISON: We can go off  
16 the record.  
17 THE VIDEOGRAPHER: Going off  
18 the record at 4:19 p.m.  
19 (Short break.)  
20 THE VIDEOGRAPHER: Back on  
21 the record at 4:34 p.m.  
22 BY MR. DAVISON:  
23 Q. All right. Dr. Whitelaw, we  
24 were earlier talking about kind of the --

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1 the time period for your review of  
 2 Mallinckrodt's anti-diversion compliance  
 3 program. Can you recall any documents  
 4 that you reviewed relating to  
 5 Mallinckrodt's anti-diversion compliance  
 6 program from prior to 2006?  
 7 A. You are asking me to recall  
 8 specific documents. I can't recall  
 9 specific documents. But you've obviously  
 10 charted it out.  
 11 One thing I wasn't clear,  
 12 when we broke, was, I did ask for  
 13 documents and did look at documents all  
 14 the way through 2018. And if you look at  
 15 the -- as you correctly noted, and we  
 16 were correctly having that discussion  
 17 right when the break took place, from  
 18 2012 onward, I haven't seen enough  
 19 documentation to be able to form an  
 20 opinion on the adequacy of an  
 21 anti-diversion program from Mallinckrodt  
 22 post 2012.  
 23 I would need to see  
 24 additional information. One of the

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1 things that would be, obviously for me  
 2 would be particularly critical, and  
 3 something I know I asked for, there  
 4 weren't any documents to be had, would  
 5 have been audits.  
 6 Q. So, sir, I want to unpack  
 7 that a little bit.  
 8 A. Sure.  
 9 Q. Are you stating today that  
 10 you cannot offer an opinion as to the  
 11 adequacy of Mallinckrodt's anti-diversion  
 12 program post 2012?  
 13 A. That is what I'm saying. I  
 14 do not have enough information to offer  
 15 an opinion for or against.  
 16 Q. All right. So at trial,  
 17 you're not planning to offer an opinion  
 18 one way or the other regarding  
 19 Mallinckrodt's anti-diversion program  
 20 post 2012, correct?  
 21 A. Unless additional  
 22 information that is relevant to this  
 23 report became available and to be  
 24 considered, I have no present intention

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1 of doing that.  
 2 Q. Okay. And if additional  
 3 information, you'd of course be required  
 4 to write a new report and we'd do this  
 5 all over again, correct?  
 6 MR. BOGLE: Object to form.  
 7 THE WITNESS: We'd certainly  
 8 be doing a supplement and having a  
 9 further conversation on a  
 10 supplement I'm sure.  
 11 BY MR. DAVISON:  
 12 Q. But you don't intend to  
 13 offer a supplement sitting here today?  
 14 MR. BOGLE: Object to form.  
 15 THE WITNESS: As I said, and  
 16 I've stated on the record right  
 17 now, no, I have no intention of  
 18 offering a supplement as we  
 19 described post 2012 on  
 20 Mallinckrodt's program without any  
 21 additional information.  
 22 BY MR. DAVISON:  
 23 Q. Thank you, sir.  
 24 So I want to -- I want to go

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1 back to the beginning of the time period  
 2 for your -- your review.  
 3 Are you offering an opinion  
 4 as to the adequacy of Mallinckrodt's  
 5 controlled substance compliance program  
 6 from 1996 to 2006?  
 7 A. Again, I think we need to  
 8 look at the documents, where they fall  
 9 out. I'm looking at your program from  
 10 just before 2007, probably up through  
 11 2012 to be precise is where I had  
 12 documents. Although I asked for  
 13 documents going all the way back in time.  
 14 Q. So your report is offering  
 15 an opinion as to Mallinckrodt's  
 16 suspicious -- excuse me. Strike that.  
 17 Your report offers an  
 18 opinion as to the effectiveness of  
 19 Mallinckrodt's anti-diversion program  
 20 from 2007 to 2012, correct?  
 21 MR. BOGLE: Object to form.  
 22 THE WITNESS: I think to be  
 23 precise, it would probably be more  
 24 like 2008 to 2012. That's the

<p style="text-align: right;">Page 941</p> <p>1 window in time that I have 2 documents, sufficient documents 3 for, to form an opinion. 4 BY MR. DAVISON: 5 Q. Thank you, sir. 6 And, sir, is that consistent 7 with your memory of the documents that 8 you reviewed? 9 A. Yes, I think it is 10 consistent with my -- the memory of the 11 documents. I'm not saying I didn't see 12 any documents. I'm saying I didn't see 13 the bulk of the documents fell out in 14 your bell curve. 15 Q. And, sir, just -- just so 16 we're clear, sitting here today, you do 17 not intend to offer an opinion as to the 18 effectiveness of Mallinckrodt's 19 anti-diversion compliance program from 20 1996 to 2007, correct? 21 MR. BOGLE: Object to form. 22 THE WITNESS: Again, I have 23 no -- unless I see some additional 24 information that warrants me to</p>	<p style="text-align: right;">Page 943</p> <p>1 Q. So you have no reason to 2 believe that Mr. O'Neill and Mr. Borelli 3 ever overlapped at Mallinckrodt, correct? 4 A. That is correct. I have -- 5 have no reason to believe that they ever 6 overlapped at Mallinckrodt. 7 Q. Sir, if you can turn to 8 Page 234 of your report. 9 A. Yes, I see it. 10 Q. You write -- I'm at the 11 third paragraph down. 12 A. Third paragraph down. 13 Q. It says "When Mallinckrodt." 14 Do you see that? 15 A. Yes. 16 Q. That's where it starts. 17 "When Mallinckrodt subsequently notified 18 distributors that it would not pay 19 chargeback on sales to multi-distributor 20 customers, Mallinckrodt failed to report 21 any of the orders that gave rise to 22 multi-distributor sales to the DEA as 23 suspicious." 24 All right, sir. Earlier</p>
<p style="text-align: right;">Page 942</p> <p>1 revisit this issue, I do not have 2 a present intention of amending my 3 report as it stands today. 4 BY MR. DAVISON: 5 Q. Thank you, sir. 6 Sir, on Page 215 of your 7 report you reference an individual named 8 Victor Borelli. I'm looking at the third 9 paragraph. It starts: "Mr. Borelli 10 worked for Mallinckrodt from 2005 to 11 2012"? 12 A. Yes, as a matter of fact I 13 see the reference. I do. 14 Q. All right. And, sir, do you 15 also recall that in your report you 16 reference an individual from Mallinckrodt 17 named Hugh O'Neill? 18 A. Yes, sir. I actually do 19 remember referencing an individual, 20 Mr. Hugh O'Neill. 21 Q. You are aware that 22 Mr. O'Neill joined Mallinckrodt in 2013? 23 A. Yes, I'm aware that 24 Mr. O'Neill joined Mallinckrodt in 2013.</p>	<p style="text-align: right;">Page 944</p> <p>1 today, we talked a little bit briefly 2 about Mallinckrodt's chargeback 3 restriction program. Are you familiar 4 with Mallinckrodt's chargeback 5 restriction program? 6 A. In broad general terms, yes. 7 But would you care to refresh my 8 recollection of the conversation. Be 9 happy to. It's -- it's been 14 hours, 10 guys. 11 Q. Fair enough. 12 Mallinckrodt at times would 13 restrict chargeback payments -- 14 A. Yes. 15 Q. -- with respect to certain 16 downstream pharmacies, do you recall 17 that? 18 A. Yes. Now I understand what 19 you are referring to. Thank you for 20 clarifying. 21 Q. Not a problem. 22 Did you analyze 23 Mallinckrodt's chargeback restriction 24 program as part of your anti-diversion</p>

<p style="text-align: right;">Page 945</p> <p>1 compliance review?</p> <p>2 MR. BOGLE: Object to form.</p> <p>3 THE WITNESS: I looked at --</p> <p>4 I looked at how Mallinckrodt was</p> <p>5 using chargeback data and</p> <p>6 incorporating it into the SOMs</p> <p>7 program as part of my review.</p> <p>8 BY MR. DAVISON:</p> <p>9 Q. And did you find flaws with</p> <p>10 Mallinckrodt's chargeback restriction</p> <p>11 program?</p> <p>12 MR. BOGLE: Object to form.</p> <p>13 THE WITNESS: I did not find</p> <p>14 flaws with the restriction</p> <p>15 program, per se. What I found a</p> <p>16 flaw with was the presence of the</p> <p>17 fact that Mallinckrodt had access</p> <p>18 to this data for a long period of</p> <p>19 time. And it wasn't until 2010</p> <p>20 roughly that you started to use it</p> <p>21 in the SOMs program. That was the</p> <p>22 issue that I was raising with</p> <p>23 chargebacks in particular.</p> <p>24 BY MR. DAVISON:</p>	<p style="text-align: right;">Page 947</p> <p>1 Q. Do you recall what</p> <p>2 distributors you're referring to as</p> <p>3 unsavory?</p> <p>4 A. I believe the ones that I'm</p> <p>5 referring to are on Page 235. So we're</p> <p>6 looking at things like Harvard Drug</p> <p>7 Group, Masters, Value Drug. I mean, we</p> <p>8 could go through the entire list if you</p> <p>9 would like.</p> <p>10 Q. And, sir, are you aware that</p> <p>11 Mallinckrodt audited Masters?</p> <p>12 MR. BOGLE: Object to form.</p> <p>13 THE WITNESS: I am aware</p> <p>14 that you had a relationship with</p> <p>15 Masters. I saw some documentation</p> <p>16 surrounding it. But I didn't see</p> <p>17 any indication that you -- that</p> <p>18 showed a -- there was a deep dive</p> <p>19 or a detailed review of Master. I</p> <p>20 didn't see that.</p> <p>21 BY MR. DAVISON:</p> <p>22 Q. So you did not see a</p> <p>23 detailed audit report from January of</p> <p>24 2011 with respect to Masters</p>
<p style="text-align: right;">Page 946</p> <p>1 Q. So -- so the flaw wasn't</p> <p>2 with what Mallinckrodt did with it, but</p> <p>3 when they started doing it. Is that</p> <p>4 fair?</p> <p>5 MR. BOGLE: Object to form.</p> <p>6 THE WITNESS: Well, some of</p> <p>7 it is a flaw of what Mallinckrodt</p> <p>8 did or didn't do with it, but the</p> <p>9 other part of the flaw is the fact</p> <p>10 that there was data that</p> <p>11 indicated, as my report indicates,</p> <p>12 and I think we can go to the page</p> <p>13 for example, on Page 235,</p> <p>14 Mallinckrodt had visibility to</p> <p>15 similar data that indicated that</p> <p>16 you were working and dealing with</p> <p>17 some pretty unsavory, shall we</p> <p>18 say, distributors, and nothing was</p> <p>19 done about it, even though you had</p> <p>20 the presence of the data inhouse</p> <p>21 until the DEA took action. So</p> <p>22 that's another issue that I have</p> <p>23 with how you used the data.</p> <p>24 BY MR. DAVISON:</p>	<p style="text-align: right;">Page 948</p> <p>1 Pharmaceutical?</p> <p>2 A. I don't rightly recall a</p> <p>3 detailed audit report from Masters</p> <p>4 Pharmaceuticals in 2011. I just don't.</p> <p>5 I'm sorry.</p> <p>6 Q. All right. That's fair. Do</p> <p>7 you recall that Mallinckrodt stopped</p> <p>8 shipping oxy 30 to Masters in the fall of</p> <p>9 2010?</p> <p>10 A. Again, my issue was that you</p> <p>11 had data on hand, and it took the DEA to</p> <p>12 take action against distributors for</p> <p>13 Mallinckrodt to essentially stop.</p> <p>14 Q. Well, sir, Masters DEA</p> <p>15 didn't take action against until June of</p> <p>16 2011. So are you aware that Mallinckrodt</p> <p>17 stopped shipping oxy 30 for a period of</p> <p>18 time starting in the fall of 2010?</p> <p>19 A. Again, I have a vague</p> <p>20 recollection of something similar to</p> <p>21 that, but I can't point to a document if</p> <p>22 that's what you're asking.</p> <p>23 Q. That's fair enough. So when</p> <p>24 you say that Mallinckrodt took no action,</p>

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1 that's not correct?

2 A. Took limited action.

3 MR. BOGLE: Object to form.

4 BY MR. DAVISON:

5 Q. In your view, Mallinckrodt

6 took limited action with respect to

7 Masters.

8 So you write here that,

9 "When Mallinckrodt subsequently notified

10 distributors that it would not pay

11 chargebacks on sales to multi-distributor

12 customers" --

13 A. Hold on, Counsel.

14 Q. I apologize.

15 A. Where are you, please.

16 Q. Fair enough.

17 A. You've lost me.

18 Q. We're still in that third

19 paragraph --

20 A. Third paragraph.

21 Q. -- of page 234?

22 A. Third paragraph, 234. Is

23 that where we are?

24 Q. Yeah, that's where we are.

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1 A. Okay. Thank you.

2 Q. "When Mallinckrodt

3 subsequently notified distributors that

4 it would not pay chargebacks on sales to

5 multi-distributor customers, Mallinckrodt

6 failed to report any of the orders that

7 gave rise to multi-distributor sales to

8 the DEA as suspicious."

9 And you cite to Ginger

10 Collier's deposition for that

11 proposition. Do you know who Ginger

12 Collier is?

13 A. I don't recall her title off

14 the top of my head. But, actually, you

15 have my notes, right?

16 MR. BOGLE: I'll give it to

17 you.

18 THE WITNESS: Can I have my

19 notes?

20 Thank you.

21 BY MR. DAVISON:

22 Q. So just so you have the --

23 the question was just, do you know what

24 Ginger Collier's title is?

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1 A. I do now.

2 Q. All right. You refreshed

3 your recollection with your notes?

4 A. I have. Director of

5 marketing.

6 Q. All right. I'm sorry. Go

7 ahead.

8 A. Director of marketing.

9 Q. Can we go ahead and mark

10 those notes?

11 MR. BOGLE: Sure.

12 MR. DAVISON: Thank you.

13 MR. BOGLE: You're welcome.

14 (Document marked for

15 identification as Exhibit

16 Whitelaw-24.)

17 BY MR. DAVISON:

18 Q. All right. So this is

19 Exhibit 24, which are copies of notes

20 that Dr. Whitelaw utilized in his

21 deposition. We'll make copies for

22 everyone after we get through.

23 A. Thank you.

24 Q. All right. So I'm going to

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1 mark Exhibit 25.

2 A. Okay.

3 (Document marked for

4 identification as Exhibit

5 Whitelaw-25.)

6 BY MR. DAVISON:

7 Q. There you go.

8 A. Thank you.

9 Q. And so again, we were on

10 Page 234. And just so you know what

11 we're looking at, you had a statement

12 that Mallinckrodt notified distributors

13 that it would not pay chargebacks, but

14 Mallinckrodt failed to report any of the

15 orders that gave rise to

16 multi-distributor sales to the DEA as

17 suspicious.

18 Just let me know when you're

19 ready, sir.

20 A. Absolutely will let you know

21 when I'm ready. Thank you.

22 Q. Sir, do you remember

23 reviewing this document?

24 A. I remember seeing this



<p style="text-align: right;">Page 953</p> <p>1 document, yes.</p> <p>2 Q. Okay. And, sir, is this an</p> <p>3 example of Mallinckrodt reporting</p> <p>4 chargeback restrictions to the DEA under</p> <p>5 21 C.F.R. 1301.74(b)?</p> <p>6 A. It is an example of</p> <p>7 notifying -- as I read the document, it's</p> <p>8 a letter that they are sending to various</p> <p>9 pharmacies with a copy to DEA of the</p> <p>10 pharmacies that they are notifying that</p> <p>11 they will no longer pay chargebacks for.</p> <p>12 Q. So is this different from</p> <p>13 what you referenced when you said,</p> <p>14 "Mallinckrodt failed to report any of the</p> <p>15 orders that gave rise to</p> <p>16 multi-distributor sales to the DEA as</p> <p>17 suspicious"?</p> <p>18 A. Well, again, I would say it</p> <p>19 is different on the grounds of what we're</p> <p>20 talking about, is you're saying I'm</p> <p>21 not -- I'm no longer -- at least as I</p> <p>22 read it, this document is a form letter,</p> <p>23 and the list of -- supposedly, I guess,</p> <p>24 the list of addressees is Attachment 1,</p>	<p style="text-align: right;">Page 955</p> <p>1 various pharmacies. But you're</p> <p>2 not giving any details behind</p> <p>3 that.</p> <p>4 BY MR. DAVISON:</p> <p>5 Q. Sir, you're aware that</p> <p>6 through ARCOS data, DEA has access to</p> <p>7 every single order that a pharmacy places</p> <p>8 from a distributor, correct?</p> <p>9 A. I am aware of the ARCOS</p> <p>10 dataset, yes.</p> <p>11 Q. And so the issue you have</p> <p>12 with what Mallinckrodt did here is that</p> <p>13 while we provided them information on</p> <p>14 pharmacies for which we had questions, we</p> <p>15 didn't provide them with the data on the</p> <p>16 orders which they already had, correct?</p> <p>17 MR. BOGLE: Object to form.</p> <p>18 THE WITNESS: I believe</p> <p>19 that's what I noted in my report,</p> <p>20 yes.</p> <p>21 BY MR. DAVISON:</p> <p>22 Q. Are you aware that in</p> <p>23 November of 2010, Mallinckrodt requested</p> <p>24 a meeting with DEA to present to DEA its</p>
<p style="text-align: right;">Page 954</p> <p>1 that this letter was all going to. Going</p> <p>2 to stop processing chargeback data.</p> <p>3 But I don't see anywhere in</p> <p>4 this letter where we talk about specific</p> <p>5 orders. What I do is specific</p> <p>6 distributors.</p> <p>7 Q. So, sir, your statement here</p> <p>8 is not that Mallinckrodt didn't report</p> <p>9 the pharmacies to DEA, but rather that</p> <p>10 Mallinckrodt is obligated to report each</p> <p>11 individual chargeback to DEA?</p> <p>12 MR. BOGLE: Object to form.</p> <p>13 THE WITNESS: I didn't say</p> <p>14 chargeback. If you notice my</p> <p>15 report was careful to say orders.</p> <p>16 BY MR. DAVISON:</p> <p>17 Q. Well, so what orders are you</p> <p>18 talking about?</p> <p>19 MR. BOGLE: Object to form.</p> <p>20 THE WITNESS: I'm talking</p> <p>21 about the orders that went to</p> <p>22 these pharmacies. What I'm saying</p> <p>23 to you is you've given notice to</p> <p>24 DEA you are cutting off these</p>	<p style="text-align: right;">Page 956</p> <p>1 suspicious order monitoring program?</p> <p>2 A. I recall a request for a</p> <p>3 meeting. I can't point to a specific</p> <p>4 document. Is there a specific place in</p> <p>5 the report that we want to look at?</p> <p>6 Q. No, I'll provide you with a</p> <p>7 document. That will make it easier.</p> <p>8 A. Great.</p> <p>9 Q. Trying to make your life</p> <p>10 easy.</p> <p>11 A. I appreciate that.</p> <p>12 Q. All right. Exhibit 26.</p> <p>13 (Document marked for</p> <p>14 identification as Exhibit</p> <p>15 Whitelaw-26.)</p> <p>16 THE WITNESS: Thank you so</p> <p>17 very much.</p> <p>18 MR. DAVISON: Just for the</p> <p>19 people on the phone, this is Bates</p> <p>20 number -- I'm sorry about that.</p> <p>21 This is MNK-T1_ --</p> <p>22 MR. BOGLE: Just -- I think</p> <p>23 you gave me something new.</p> <p>24 BY MR. DAVISON:</p>

<p style="text-align: right;">Page 957</p> <p>1 Q. MNK-T1_0000421974. 2 A. I see the document, yes. 3 Q. Sir, do you have a 4 recollection of reviewing this document 5 in preparation of your report? 6 A. I do recollect seeing this 7 document in the past, yes. 8 Q. Okay. And, sir, this looks 9 like notes from a meeting at DEA 10 St. Louis office, 11/01/10, correct? 11 A. That's what it appears to 12 be, yes. That's certainly what the title 13 of the document is. 14 Q. All right. You have no 15 reason to doubt that's what this document 16 is? 17 A. No, I don't have any reason 18 to doubt it. 19 Q. And under overview, it 20 states, "Mallinckrodt started the meeting 21 by indicating the appointment had been 22 requested to discuss Mallinckrodt's 23 enhancements to suspicious order 24 monitoring program, further to provide</p>	<p style="text-align: right;">Page 959</p> <p>1 things I've looked at like deposition 2 testimony, et cetera. 3 So it's part of what I 4 relied on. 5 Q. Fair enough. 6 So this document is no 7 different from the other e-mails that are 8 cited in -- in your report. You rely on 9 that, the transcripts, everything we 10 discussed earlier with our methodology, 11 correct? 12 A. Correct. 13 Q. If you read down -- 14 actually, let's -- let's move up. The 15 DEA attendees. One of the attendees is 16 Scott Collier, diversion program manager 17 (DPM). 18 A. I see that. 19 Q. Do you see that? 20 A. Yes, I do, sir. 21 Q. Do you know who Scott 22 Collier is? 23 A. Not personally. I know who 24 he is as represented here.</p>
<p style="text-align: right;">Page 958</p> <p>1 DEA new statistical data that has been 2 gathered from sales chargeback monitoring 3 system." 4 Did I read that correctly? 5 A. I believe you did read that 6 correctly. 7 Q. All right. Sir, do you have 8 any reason to doubt that that's the 9 reason Mallinckrodt requested the 10 meeting? 11 MR. BOGLE: Object to form. 12 THE WITNESS: All I know is 13 what's written here in front of me 14 on the document. So I can't make 15 any other judgments than what I'm 16 seeing and reading on the 17 document. 18 BY MR. DAVISON: 19 Q. And that's true for -- for 20 every document you reviewed in this case, 21 correct? 22 A. I have to rely on the 23 documents if that's what you're asking, 24 yes, in -- in conjunction with the other</p>	<p style="text-align: right;">Page 960</p> <p>1 Q. Do you know where in the DEA 2 hierarchy a diversion program manager is 3 compared to a diversion investigator? 4 A. Well, I would assume a 5 diversion program manager is higher than 6 a diversion investigator, but exactly how 7 many steps separate the two, I don't know 8 off the top of my head. 9 Q. All right. And if 10 Mr. Rafalski testified that the diversion 11 program manager is -- is two steps up 12 from a diversion investigator, you'd have 13 no reason to doubt that? 14 A. I would have no reason to 15 doubt that, no. 16 Q. And so if you go -- the 17 general feedback from DEA St. Louis, it 18 states, "The DPM commented that the 19 information Mallinckrodt presented was 20 the best suspicious order monitoring 21 process he has seen to date and what he 22 expected from Mallinckrodt as an industry 23 leader." 24 Did I read that correctly?</p>

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<p>1 A. I do believe that you did 2 read that correctly.</p> <p>3 Q. Sir, do you have any reason 4 to doubt that the diversion program 5 manager said that about Mallinckrodt's 6 suspicious order monitoring program in 7 2010?</p> <p>8 MR. BOGLE: Object to form.</p> <p>9 THE WITNESS: Could you 10 be -- could you restate the 11 question for me, please?</p> <p>12 BY MR. DAVISON:</p> <p>13 Q. Do you have any reason to 14 doubt that the diversion program manager 15 from DEA St. Louis stated that 16 "Mallinckrodt's suspicious order 17 monitoring process was the best that he 18 had seen to date and what he expected 19 from Mallinckrodt as an industry leader"?</p> <p>20 MR. BOGLE: Same objection.</p> <p>21 THE WITNESS: Again, all I 22 can comment on is this is a 23 document that appears -- which I'm 24 not even sure who created the</p>	<p>1 clearer than that, but I only have 2 what's through knowledge of the 3 e-mails and the documents that I 4 see in front of me, as well as any 5 corresponding deposition 6 testimony, and any other documents 7 that, you know, are interplayed or 8 attachments or whatever else I 9 have to work with.</p> <p>10 BY MR. DAVISON:</p> <p>11 Q. And the depositions that you 12 reviewed relating to Mallinckrodt 13 employees, those were taken by 14 plaintiffs' counsel, correct?</p> <p>15 A. Yes, Counsel, I believe they 16 were.</p> <p>17 Q. Did plaintiffs' counsel ever 18 ask any of Mallinckrodt's employees about 19 this document?</p> <p>20 A. Honestly I can't -- I've 21 reviewed quite a few depositions and I 22 don't honestly remember the details of 23 every deposition, so I can't tell you off 24 the top of my head, Counsel.</p>
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<p>1 document, because it's not clear 2 from the document that I'm 3 reading -- but assuming it's a 4 Mallinckrodt employee who created 5 it, it is their recollection of 6 the meeting and I have no way of 7 knowing whether that's an accurate 8 statement by Mr. Collier or not. 9 All I know is what I'm reading 10 here.</p> <p>11 BY MR. DAVISON:</p> <p>12 Q. And you didn't make any 13 attempt to interview Mr. Collier about 14 it, correct?</p> <p>15 A. No, sir, I did not interview 16 Mr. Collier.</p> <p>17 Q. And the same is true with 18 respect to every other e-mail that you 19 cited in your report, you only have the 20 knowledge of what's on the document, 21 right?</p> <p>22 MR. BOGLE: Object to form.</p> <p>23 THE WITNESS: As I said, I 24 think we -- I think I was a little</p>	<p>1 Q. So nothing stands out in 2 your mind as this being asked about in a 3 deposition, correct?</p> <p>4 A. Nothing stands out that I 5 seem to remember.</p> <p>6 Q. And so there's no deposition 7 testimony that would call into 8 question -- strike that.</p> <p>9 Can you think of any 10 deposition testimony that you reviewed 11 that would call into question the 12 accuracy of the statement that the DPM 13 commented that "the information 14 Mallinckrodt presented was the best 15 suspicious order monitoring process he 16 has seen to date and what he expected 17 from Mallinckrodt as an industry leader"?</p> <p>18 MR. BOGLE: Object to form.</p> <p>19 THE WITNESS: Again, 20 Counsel, I don't recall anything 21 in a deposition transcript to that 22 effect.</p> <p>23 BY MR. DAVISON:</p> <p>24 Q. Now, if the DPM comment --</p>

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1 made that statement, do you think  
2 Mallinckrodt could have relied upon it?  
3 MR. BOGLE: Object to form.  
4 THE WITNESS: Again, I think  
5 it goes back to saying, if he made  
6 the comment, he made the comment.  
7 I don't know whether he made the  
8 comment or he didn't. So I really  
9 can't comment one way or the  
10 other.  
11 BY MR. DAVISON:  
12 Q. And, sir, did you take this  
13 document into account when making your  
14 conclusions about the effectiveness of  
15 Mallinckrodt's anti-diversion compliance  
16 program in 2010?  
17 A. Yes, I did.  
18 Q. But you didn't cite this  
19 document anywhere in your report,  
20 correct?  
21 A. No, sir, I did not.  
22 Q. Do you think it's not  
23 relevant what DEA says about a  
24 registrant's suspicious order monitoring

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1 program?  
2 MR. BOGLE: Object to form.  
3 Mischaracterizes the document, as  
4 to speaking to DEA as a whole.  
5 THE WITNESS: Could you  
6 restate the question?  
7 BY MR. DAVISON:  
8 Q. Yeah. Do you think it's not  
9 relevant what a diversion program manager  
10 of DEA says about a registrant's  
11 suspicious order monitoring program?  
12 A. I didn't say that,  
13 Counselor.  
14 What I said was I can't tell  
15 from this document, number one, whether  
16 or not he actually made the comment or  
17 not; and number two, in making that  
18 comment, I have no idea what that -- if  
19 there was any surrounding context is,  
20 because I don't see here, and I don't  
21 recall seeing what exactly was the  
22 context of the conversation as well as  
23 the presentation that was given. So I  
24 don't know.

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1 Q. So it's fair to say under  
2 your methodology, you would not rely upon  
3 meeting notes, correct?  
4 MR. BOGLE: Object to form.  
5 Misstates testimony.  
6 THE WITNESS: I don't think  
7 that that's what I'm saying. I'm  
8 saying to you -- you're asking --  
9 again, what exactly are you asking  
10 me, Counsel?  
11 BY MR. DAVISON:  
12 Q. Do you think it's not  
13 relevant what a diversion program manager  
14 of DEA says about a registrant's  
15 suspicious order monitoring program?  
16 MR. BOGLE: Object to form.  
17 THE WITNESS: I would say  
18 that it is something to take into  
19 account.  
20 BY MR. DAVISON:  
21 Q. So you took this into  
22 account in coming to your conclusion that  
23 Mallinckrodt's anti-diversion compliance  
24 program in 2010 was not effective,

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1 correct?  
2 A. It was --  
3 MR. BOGLE: Asked and  
4 answered. You can answer again.  
5 THE WITNESS: It was one of  
6 many things I considered, but yes,  
7 I took it into account.  
8 BY MR. DAVISON:  
9 Q. The next page states, "While  
10 DEA cannot technically approve the  
11 suspicious order monitoring program of  
12 any registrant, the message from DEA was  
13 that Mallinckrodt was on" -- "is on the  
14 right track."  
15 Did I read that correctly?  
16 A. Yes, I believe you did read  
17 the notes correctly.  
18 Q. And you took this into  
19 account in coming to your conclusion that  
20 Mallinckrodt's anti-diversion compliance  
21 program was not effective in 2010,  
22 correct?  
23 MR. BOGLE: Objection.  
24 Asked and answered.

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1 MR. DAVISON: It's a  
2 different statement.  
3 THE WITNESS: Same answer as  
4 before.  
5 BY MR. DAVISON:  
6 Q. And you didn't cite to that  
7 statement in your report either?  
8 A. No, Counselor, I did not  
9 cite to that statement in my report  
10 either.  
11 Q. Do you think this document  
12 is important?  
13 MR. BOGLE: Object to form.  
14 THE WITNESS: Can you be a  
15 lot more specific?  
16 BY MR. DAVISON:  
17 Q. Sure.  
18 A. Because, I mean, that's a --  
19 Q. Sure. We'll go there.  
20 A. You can drive a truck  
21 through that.  
22 Q. You talked earlier about the  
23 importance of looking at communications  
24 with your regulator when you're analyzing

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1 compliance?  
2 A. Right. I did.  
3 Q. So this is a memo of  
4 communications with Mallinckrodt's  
5 regulator -- excuse me -- regulator  
6 relating to its controlled substances  
7 compliance, correct?  
8 MR. BOGLE: Object to form.  
9 THE WITNESS: No, actually,  
10 I don't see it as a communication  
11 with Mallinckrodt's regulator.  
12 What I see it is a recollection of  
13 meeting notes between Mallinckrodt  
14 and the DEA. I don't see this  
15 as -- I don't see this, these  
16 statements being made on official  
17 DEA letterhead signed by the  
18 diversion program manager. I  
19 don't see anything official about  
20 it.  
21 So I -- other than the fact  
22 that there was a meeting, and this  
23 is the person's recollection of  
24 the meeting that occurred, I'm

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1 afraid I don't see this as an  
2 official communication, if that's  
3 where you're going.  
4 BY MR. DAVISON:  
5 Q. No, I didn't -- I didn't ask  
6 that. But I just want to understand  
7 this. So you haven't seen any notes from  
8 DEA about this meeting that would  
9 contradict this, correct?  
10 MR. BOGLE: Object to form.  
11 THE WITNESS: I haven't seen  
12 any meeting notes period that  
13 would give me a direction of  
14 whether it occurred, didn't occur,  
15 this was said, that was said. I  
16 have nothing.  
17 BY MR. DAVISON:  
18 Q. And you haven't spoken to  
19 anyone DEA -- at DEA about this meeting?  
20 MR. BOGLE: Objection.  
21 THE WITNESS: No, sir. I  
22 have not spoken to anyone at DEA  
23 about this particular meeting.  
24 BY MR. DAVISON:

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1 Q. So the only evidence that  
2 you have about this meeting is this  
3 document, correct?  
4 MR. BOGLE: Object to form.  
5 THE WITNESS: The only  
6 evidence I have about this meeting  
7 is what I've seen right here.  
8 BY MR. DAVISON:  
9 Q. All right. And although you  
10 have nothing that contradicts this  
11 evidence, you stated that because it's  
12 meeting notes, you're not sure what  
13 anyone said, correct?  
14 MR. BOGLE: Object to form.  
15 THE WITNESS: I'm saying to  
16 you -- you're saying this is --  
17 you have represented or at least  
18 were representing, if I understood  
19 you correctly, that this is what  
20 DEA -- this was DEA's position to  
21 Mallinckrodt at that time, and I'm  
22 saying that I can't ascertain  
23 that. I can tell you that this is  
24 somebody's recollection of what



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1 they thought was said in the  
2 meeting by the DPM. Whether it  
3 was or was not, I don't know.  
4 BY MR. DAVISON:  
5 Q. Sir, do you believe that  
6 this was actually stated at the meeting?  
7 MR. BOGLE: Objection.  
8 Asked and answered.  
9 THE WITNESS: I have told  
10 you I don't have an opinion one  
11 way or the other. I don't have  
12 enough information to work from,  
13 as to whether or not this is an  
14 accurate -- this is what was said  
15 in the meeting.  
16 BY MR. DAVISON:  
17 Q. So to have enough  
18 information, when you have meeting notes,  
19 you would need someone else's notes as  
20 well to make that --  
21 A. I'd need more corroboration.  
22 It could be notes. It could be  
23 testimony, it could be other things to  
24 look at other than just a single --

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1 Q. All right. So a single  
2 piece of meeting notes is not sufficient  
3 for you?  
4 MR. BOGLE: Object to form.  
5 That's a question?  
6 BY MR. DAVISON:  
7 Q. Yes. Let me rephrase.  
8 MR. BOGLE: I just didn't  
9 know if it was a question.  
10 BY MR. DAVISON:  
11 Q. A single set of meeting  
12 notes without corroborating evidence is  
13 not sufficient in your methodology for  
14 reviewing a controlled substance  
15 compliance program?  
16 MR. BOGLE: Object to form.  
17 Misstates his testimony.  
18 THE WITNESS: Again, that's  
19 not what I'm saying. I'm saying a  
20 single piece of meeting notes made  
21 by a registrant purporting to bind  
22 the DEA to a policy statement, I  
23 would need to see something more  
24 official or more corroborating

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1 evidence to say whether or not  
2 that actually was said or not. I  
3 don't know. I honestly don't  
4 know.  
5 BY MR. DAVISON:  
6 Q. Is it fair to say that you  
7 would take the same approach if you had a  
8 single piece of meeting notes made by a  
9 Detroit diversion investigator purporting  
10 to bind the DEA to a policy statement?  
11 MR. BOGLE: Object to form.  
12 THE WITNESS: If I had a  
13 single piece of meeting notes  
14 purporting to state -- to state  
15 DEA policy that that was what's  
16 stated in the meeting, I would  
17 still want to see more additional  
18 evidence.  
19 BY MR. DAVISON:  
20 Q. Sir, based on your 30 years  
21 of -- of experience, I assume you are  
22 familiar with memorandum of agreements in  
23 the pharmaceutical industry, correct?  
24 A. Yes, I am.

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1 Q. And these are essentially  
2 agreements between a pharmaceutical  
3 industry member or company and the  
4 government, correct?  
5 A. It's a broad  
6 characterization, but I think it's a fair  
7 characterization.  
8 Q. And in those agreements,  
9 let's use the term "manufacturer" to make  
10 it a little -- little easier here.  
11 A. Okay. That would be  
12 helpful.  
13 Q. A manufacturer could agree  
14 in an MOA to do more than is required by  
15 the statute, correct?  
16 MR. BOGLE: Objection.  
17 Vague and overbroad.  
18 THE WITNESS: Could you be a  
19 little more specific on where you  
20 are trying to go? Because I'm not  
21 sure of your question.  
22 BY MR. DAVISON:  
23 Q. Well, sure. So let's talk  
24 about the CSA. Actually let's talk about

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1 the suspicious ordering monitoring  
2 regulation. Are you familiar with that,  
3 we talked about it earlier?  
4 A. I am familiar with that,  
5 certainly.  
6 Q. So a manufacturer could  
7 agree in an MOA to do more than is  
8 required by the suspicious order  
9 monitoring regulation?  
10 MR. BOGLE: Object to form.  
11 THE WITNESS: Again, we're  
12 talking about an incredibly broad  
13 brush hypothetical. I would  
14 assume --  
15 BY MR. DAVISON:  
16 Q. Sure. Let's -- let's --  
17 A. -- in regards to any  
18 standard, a manufacturer could decide to  
19 go above and beyond, yes.  
20 Q. And it could have entered  
21 into a memorandum of agreement to do  
22 that, correct?  
23 MR. BOGLE: Object to form.  
24 THE WITNESS: Assuming the

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1 other side was willing to agree to  
2 it, I would assume you could enter  
3 into an agreement.  
4 BY MR. DAVISON:  
5 Q. So for example, if the CSA  
6 requires that a manufacturer check the  
7 locks on its vaults once per day, a  
8 manufacturer could enter into an MOA that  
9 they are going to check the locks on its  
10 vault four times a day, correct?  
11 A. Well, they certainly could  
12 propose it. Whether or not that gets  
13 agreed to, but --  
14 Q. Fair enough. And if the  
15 government agreed?  
16 A. Yes, then you'd enter into  
17 an agreement.  
18 MR. BOGLE: Wait for him to  
19 finish the question.  
20 BY MR. DAVISON:  
21 Q. And you'd agree with me,  
22 sir, that that does not then mean that  
23 the CSA requires everyone, all  
24 manufacturers, to check the locks on

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1 their vaults four times per day?  
2 MR. BOGLE: Object to form.  
3 THE WITNESS: I would say  
4 the agreement -- again, it would  
5 depend on how the agreement is  
6 actually written.  
7 But the agreement -- if the  
8 agreement is only between two  
9 parties I would say that we are  
10 talking about the two parties.  
11 But it does -- I think you need to  
12 be careful here, Counsel, because  
13 at least in my world, we look  
14 at -- for example, let's take a  
15 Corporate Integrity Agreement.  
16 It's not binding, but it does  
17 provide guidance as to where DEA's  
18 thinking is.  
19 And guidance as to what is  
20 industry leading practice, so  
21 other manufacturers should, in  
22 fact, take note of it.  
23 BY MR. DAVISON:  
24 Q. So it's guidance, not an

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1 obligation, correct?  
2 MR. BOGLE: Object to form.  
3 THE WITNESS: Between the  
4 parties that are not -- the  
5 parties of the memorandum, yes.  
6 But it -- it's data that should be  
7 factored in.  
8 BY MR. DAVISON:  
9 Q. Fair enough.  
10 MR. DAVISON: Let's go ahead  
11 and we'll take a quick break.  
12 There's only ten minutes left. So  
13 if we can go off the record.  
14 THE VIDEOGRAPHER: Going off  
15 the record. 5:11 p.m.  
16 (Short break.)  
17 THE VIDEOGRAPHER: We are  
18 back on the record at 5:35 p.m.  
19 BY MR. DAVISON:  
20 Q. All right. Dr. Whitelaw, I  
21 do have one more document to discuss  
22 today.  
23 A. Okay.  
24 Q. I -- I think we talked, you

<p style="text-align: right;">Page 981</p> <p>1 agreed kind of your opinion starts in  2 2007. So I want to start in 2007 with  3 the DEA guidance that was provided in a  4 December guidance level -- guidance  5 document.  6 The Bates number is USDEA  7 00005941. Sir, you can go ahead and take  8 a look at that document.  9 A. Okay.  10 Q. Sir, have you seen this  11 document before?  12 A. Yes, sir, I have actually.  13 Q. Have you seen this document  14 prior to your engagement in this  15 litigation?  16 A. I can't rightly recall  17 whether I've seen it prior to this  18 litigation, but -- so I can't -- I can't  19 answer that for you, sorry.  20 Q. And, sir, this is guidance  21 that's on a DEA letterhead, correct?  22 A. Yes, as it appears to be.  23 Q. And it says, "Letter is  24 being sent to every entity in the United</p>	<p style="text-align: right;">Page 983</p> <p>1 sentence that reads, "The determination  2 of whether an order is suspicious depends  3 not only on the ordering patterns of the  4 particular customer, but also on patterns  5 of the registrant's customer, based on  6 patterns throughout the relevant segment  7 of the regulated industry."  8 Q. And we talked earlier, a  9 manufacturer registrant's customer base  10 are distributors, correct?  11 A. We talked earlier that  12 that's their direct customer, yes.  13 Q. You're not claiming now that  14 Mallinckrodt's are selling directly to  15 individual pharmacies, correct?  16 A. I am not claiming that  17 Mallinckrodt is selling to individual  18 pharmacies.  19 Q. All right. And this states,  20 I think the -- the sentence you read  21 says, "The determination of whether an  22 order is suspicious depends not only on  23 the ordering patterns of the particular  24 customer, but also on the patterns of the</p>
<p style="text-align: right;">Page 982</p> <p>1 States registered with the Drug  2 Enforcement Administration, DEA, to  3 manufacture or distribute controlled  4 substances."  5 Do you see that?  6 A. I do see that, yes.  7 Q. Now sir, this is the DEA  8 guidance from December 20, 2007. Do you  9 see anything in this guidance that says a  10 manufacturer needs to look at chargeback  11 data?  12 A. I do not see anything in  13 this document where the word -- I do not  14 see the words "chargeback data" in this  15 discussion.  16 Q. Is there anything in this  17 document that you would interpret to  18 require a manufacturer to review  19 chargeback data?  20 A. Yes, actually I would.  21 Q. Where is that, sir?  22 A. I would look on Page 2. I  23 would look at the top of the page for  24 starters. And I would look at the</p>	<p style="text-align: right;">Page 984</p> <p>1 registrant's customer base and the  2 patterns throughout the relevant segment  3 of the regulated industry."  4 Sir, a chargeback is not an  5 order, correct?  6 MR. BOGLE: Object to form.  7 THE WITNESS: I would say a  8 chargeback is not an order.  9 BY MR. DAVISON:  10 Q. All right. And this does  11 not reference a chargeback, correct?  12 A. This does not reference the  13 chargeback.  14 Q. And, sir, is there anything  15 in this letter that explicitly states  16 that a manufacturer must know its  17 customer's customer?  18 A. I do not see the words "know  19 your customer's customer" in this  20 particular letter that you are showing  21 me.  22 Q. And there's nothing in here  23 stating that a manufacturer needs to  24 monitor pharmacies that order from</p>

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1 distributors, correct?  
2 MR. BOGLE: Object to form.  
3 THE WITNESS: Could you  
4 restate the question for me  
5 please, Counsel?  
6 BY MR. DAVISON:  
7 Q. And there's nothing in here  
8 stating that a manufacturer needs to  
9 monitor pharmacies that order from  
10 distributors, correct?  
11 MR. BOGLE: Object to form.  
12 THE WITNESS: I do not see  
13 those words in this letter that --  
14 in this document that you're  
15 showing me right at this moment.  
16 BY MR. DAVISON:  
17 Q. Sir, would you agree that  
18 the focus of this letter is on monitoring  
19 orders from a registrant's customer?  
20 MR. BOGLE: Object to form.  
21 THE WITNESS: No, Counselor,  
22 I would disagree with that. I  
23 think it's on anti-diversion in  
24 general and suspicious -- and

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1 suspicious order monitoring as  
2 well, but I believe we are talking  
3 about -- because as he starts out  
4 in his letter on the first full  
5 paragraph -- sorry, second full  
6 paragraph on the first page, he  
7 talks about the controlled  
8 substances statute and where we  
9 were talking about that, those  
10 favorite words of yours, of the  
11 anti-diversion program, having an  
12 effective anti-diversion program.  
13 BY MR. DAVISON:  
14 Q. All right. So I think your  
15 statement was that this covers  
16 anti-diversion in general as well as  
17 suspicious order monitoring.  
18 Focusing on suspicious  
19 ordering monitoring, would you agree that  
20 the focus of this letter with respect to  
21 suspicious order monitoring is on  
22 monitoring a registrant's direct  
23 customers?  
24 MR. BOGLE: Object to form.

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1 THE WITNESS: No, Counselor.  
2 I just see the term "customer." I  
3 don't see customers, indirect  
4 customers. I just see customers.  
5 So I'm sorry. I don't.  
6 BY MR. DAVISON:  
7 Q. I think you said already  
8 that for a manufacturer, its customers  
9 are distributors, correct?  
10 MR. BOGLE: Object to form.  
11 THE WITNESS: In most cases,  
12 yes, that's what I did say.  
13 BY MR. DAVISON:  
14 Q. All right. So you're not  
15 saying that manufacturers are selling to  
16 individual pharmacies?  
17 MR. BOGLE: Object to form.  
18 THE WITNESS: I was saying  
19 to you that I didn't --  
20 Mallinckrodt wasn't selling to  
21 individual pharmacies that I was  
22 aware of.  
23 BY MR. DAVISON:  
24 Q. Fair enough. That's the

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1 only one that you reviewed, correct?  
2 A. Correct.  
3 Q. All right. Are you aware of  
4 any official DEA guidance after this  
5 December 20, 2007 -- excuse me. Strike  
6 that.  
7 Are you aware of any  
8 official DEA guidance after this  
9 December 20, 2007, letter but before  
10 Mallinckrodt started monitoring  
11 chargebacks that stated a manufacturer  
12 needs to know its customer's customers?  
13 MR. BOGLE: Object to form.  
14 THE WITNESS: Counselor, let  
15 me go through my report.  
16 BY MR. DAVISON:  
17 Q. So sitting here today,  
18 without going through your report, you're  
19 not aware of any DEA guidance that stated  
20 that?  
21 MR. BOGLE: Object to form.  
22 THE WITNESS: Counsel, as I  
23 said, I need to look at my report  
24 if you want me to answer the

<p style="text-align: right;">Page 989</p> <p>1 question.</p> <p>2 BY MR. DAVISON:</p> <p>3 Q. So you can't answer the</p> <p>4 question without looking at your report?</p> <p>5 MR. BOGLE: Object to form.</p> <p>6 THE WITNESS: I want to be</p> <p>7 sure on what I'm answering to you,</p> <p>8 so I would like to look at my</p> <p>9 report.</p> <p>10 (Document marked for</p> <p>11 identification as Exhibit</p> <p>12 Whitelaw-27.)</p> <p>13 BY MR. DAVISON:</p> <p>14 Q. Okay. Sir, are you aware of</p> <p>15 DEA ever sending a letter like this to</p> <p>16 manufacturers telling them that they need</p> <p>17 to monitor chargeback data?</p> <p>18 MR. BOGLE: Object to form.</p> <p>19 THE WITNESS: Could you ask</p> <p>20 that question again, please.</p> <p>21 BY MR. DAVISON:</p> <p>22 Q. Yeah, no problem. Are you</p> <p>23 aware of DEA ever sending a letter like</p> <p>24 Exhibit 27, telling manufacturers that</p>	<p style="text-align: right;">Page 991</p> <p>1 as guidance, correct?</p> <p>2 A. Yes, we did talk about that.</p> <p>3 Q. And this letter here, would</p> <p>4 you agree that this is a piece of</p> <p>5 guidance provided to industry?</p> <p>6 A. I would agree that it looks</p> <p>7 like an official piece of guidance</p> <p>8 provided to industry, yes.</p> <p>9 Q. And guidance doesn't</p> <p>10 necessarily create an obligation,</p> <p>11 correct?</p> <p>12 MR. BOGLE: Object to form.</p> <p>13 THE WITNESS: When you say</p> <p>14 "obligation," could you be a bit</p> <p>15 more specific?</p> <p>16 BY MR. DAVISON:</p> <p>17 Q. Yeah. Guidance doesn't</p> <p>18 necessarily create a new obligation under</p> <p>19 a statute?</p> <p>20 MR. BOGLE: Object to form.</p> <p>21 THE WITNESS: I believe</p> <p>22 guidance expounds on existing</p> <p>23 statutes and regulations and</p> <p>24 provides additional clarity.</p>
<p style="text-align: right;">Page 990</p> <p>1 they're obligated to monitor chargeback</p> <p>2 data?</p> <p>3 MR. BOGLE: Object to form.</p> <p>4 THE WITNESS: Well, I think</p> <p>5 I'm going to have to break your --</p> <p>6 break your question down into two</p> <p>7 parts. I'm aware of the fact that</p> <p>8 letters like this were sent to</p> <p>9 manufacturers. I don't recall in</p> <p>10 the letters that I have seen,</p> <p>11 seeing anything referencing --</p> <p>12 seeing the words "chargeback</p> <p>13 data."</p> <p>14 BY MR. DAVISON:</p> <p>15 Q. And, sir, earlier we talked</p> <p>16 about how corporate integrity agreements</p> <p>17 and MOAs are guidance, correct?</p> <p>18 MR. BOGLE: Object to form.</p> <p>19 THE WITNESS: Well --</p> <p>20 BY MR. DAVISON:</p> <p>21 Q. Or strike that.</p> <p>22 Earlier today we talked</p> <p>23 about how MOAs can be used by others in</p> <p>24 the industry that have not signed the MOA</p>	<p style="text-align: right;">Page 992</p> <p>1 MR. BOGLE: We are at</p> <p>2 14 hours.</p> <p>3 MR. DAVISON: All right. I</p> <p>4 see my time is up. I know that a</p> <p>5 number of individuals did not have</p> <p>6 enough time to question the</p> <p>7 witness, given the multitude of</p> <p>8 opinions, the length of the</p> <p>9 report, and the witness's answers.</p> <p>10 So we reserve the right to reopen</p> <p>11 the deposition as necessary. Off</p> <p>12 the record.</p> <p>13 THE VIDEOGRAPHER: Going off</p> <p>14 the record 5:46 p.m.</p> <p>15 (Brief pause.)</p> <p>16 THE VIDEOGRAPHER: Back on</p> <p>17 the record at 5:48 p.m.</p> <p>18 - - -</p> <p>19 EXAMINATION</p> <p>20 - - -</p> <p>21 BY MR. BOGLE:</p> <p>22 Q. Hi, Dr. Whitelaw. I've got</p> <p>23 a -- my name is Brandon Bogle. I've got</p> <p>24 a few follow-up questions for you. Can</p>



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1 you go back to Exhibit 26 for me, please?  
2 A. Yes, sir. I have it in  
3 front of me.  
4 Q. Okay. Do you recall being  
5 asked some questions about this document?  
6 A. Yes, I do.  
7 Q. Okay. And do you recall  
8 specifically being asked some questions  
9 about statements from an individual from  
10 DEA, Scott Collier?  
11 A. Yes, I do recall that.  
12 Q. Okay. And this document,  
13 does it indicate what information was  
14 presented by Mallinckrodt at this meeting  
15 to Scott Collier?  
16 A. No, sir, it does not.  
17 Q. Okay. And could you go  
18 specifically to Page 209 of your report  
19 for me, please?  
20 A. Yes, sir. I'm there.  
21 Q. Okay. And if you look at  
22 the last paragraph here on this page you  
23 note, "In 2017, Mallinckrodt entered into  
24 an agreement with the DEA to resolve the

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1 agency's ongoing investigations and  
2 settled allegations made by the DEA that  
3 the company, prior to 2012, failed to  
4 maintain and operate an effective  
5 anti-diversion program."  
6 Did I read that correctly?  
7 A. Yes, sir, I think you did.  
8 Q. And you see there, you cite  
9 to a Footnote 1238?  
10 A. I do.  
11 Q. Okay. And in Footnote 1238  
12 if you see in the last parenthetical, you  
13 note, "The investigation related to the  
14 settlement" -- the formal investigation  
15 DEA -- "The formal DEA investigation  
16 began in September of 2011."  
17 Do you see that?  
18 A. Yes, sir, I do.  
19 Q. Okay. The information that  
20 you discussed related to the 2017  
21 settlement agreement and the time period  
22 in which the investigation related to it  
23 occurred, how does that impact the  
24 statements for -- the alleged statements

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1 from Scott Collier in Exhibit 26 in your  
2 view?  
3 MR. DAVISON: Objection to  
4 form.  
5 THE WITNESS: Basically what  
6 this says to me is that this was  
7 not -- his position, assuming this  
8 was, in fact, what he said at that  
9 time in that report and at that  
10 statement in that meeting is not  
11 consistent with DEA's position  
12 overall, as evidenced by the fact  
13 that they commenced an  
14 investigation and subsequently  
15 Mallinckrodt settled with the DEA  
16 in 2017 for controlled substances  
17 issues and anti-diversion issues.  
18 BY MR. BOGLE:  
19 Q. Okay. Do you recall earlier  
20 in your discussion with Mallinckrodt's  
21 counsel, providing testimony to the  
22 effect that you were not expressing any  
23 opinions about Mallinckrodt's suspicious  
24 order monitoring program prior to 2008?

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1 A. Yes, I do recall that.  
2 Q. Okay. Could I direct you to  
3 Page 219 of your report please?  
4 A. Absolutely. I am there.  
5 Q. And if you see the first  
6 sentence on this page it says, "Prior to  
7 2008, Mallinckrodt's anti-diversion  
8 program was marked by an absence of  
9 formal written standards."  
10 Do you see that statement?  
11 A. Yes, I do.  
12 Q. Is that a statement that you  
13 wrote in this report?  
14 A. Yes, it's a statement I  
15 wrote in this report.  
16 Q. Do you still believe that  
17 statement to be true today?  
18 A. Yes, I still believe that  
19 statement to be true today.  
20 Q. Okay. And if we can now go  
21 to Page 216 of your report.  
22 If you see under 14.4.2 A,  
23 the first sentence there states, "Prior  
24 to March 2008, there is scant evidence

<p style="text-align: right;">Page 997</p> <p>1 that Mallinckrodt had a formally 2 designated SOM team." 3 Do you see that? 4 A. Yes, I do. 5 Q. Do you write that statement 6 in your report? 7 A. Yes. 8 Q. Do you still hold that 9 opinion today? 10 A. Yes, I still believe that's 11 correct. 12 Q. So given these two opinions, 13 Number 1 that prior to March 2008 there 14 is scant evidence that Mallinckrodt had a 15 formally designated SOM team, and that 16 prior to 2008 there was an absence of 17 formal written standards surrounding 18 anti-diversion, what does that say in 19 your mind concerning whether you actually 20 are offering opinions that there were 21 defects in Mallinckrodt's anti-diversion 22 program prior to 2008? 23 MR. DAVISON: Objection to 24 form.</p>	<p style="text-align: right;">Page 999</p> <p>1 A. That is correct. 2 Q. "But they worked to 3 configure a program that only addressed 4 the bare minimums and did not interfere 5 with ABC's pursuit of ever increasing 6 revenues." 7 Do you see that statement? 8 A. Yes, sir, I do see the 9 statement. 10 Q. Do you recall being asked 11 some questions earlier today about this 12 statement concerning ABC doing the bare 13 minimums in this regard? 14 A. Yes, I do recall having a 15 conversation on that. 16 Q. Okay. And -- and in this 17 report and your prior testimony today on 18 that issue, what were you intending to 19 convey about ABC doing the bare minimum 20 in this context? 21 MS. CASTLES: Object to 22 form. 23 MR. HYNES: Object to form. 24 MR. MELTON: Object to form.</p>
<p style="text-align: right;">Page 998</p> <p>1 MS. CASTLES: Object to 2 form. 3 MS. MONAGHAN: Object to 4 form. 5 THE WITNESS: I would offer 6 the opinion that, in fact, it 7 is -- there are defects in 8 Mallinckrodt's program prior to 9 2008 based on this evidence and 10 the fact that there -- there is 11 nothing to indicate there -- the 12 existence of that formal program. 13 BY MR. BOGLE: 14 Q. And the last thing I want to 15 discuss with you, if you can go to 16 Page 128 of your report. 17 A. All right. Flipping there. 18 Okay. Got it. 19 Q. Okay. If we can go to the 20 third paragraph here. 21 A. Okay. 22 Q. You state, "But they" -- and 23 the "they" here you are talking about 24 ABC, correct?</p>	<p style="text-align: right;">Page 1000</p> <p>1 MS. MONAGHAN: Object to 2 form. 3 THE WITNESS: What I was 4 trying to convey, and apparently, 5 again, I don't think I was very 6 clear. What I was trying to 7 convey, when I said bare minimums, 8 I mean just the bare minimum, in 9 other words, just what's necessary 10 to -- to avoid an enforcement 11 action or other regulatory 12 sanctions from DEA. 13 BY MR. BOGLE: 14 Q. During the review period for 15 ABC specifically, what is your opinion 16 concerning whether ABC acted as a 17 responsible and reasonable distributor as 18 to their SOMs and anti-diversion program? 19 UNIDENTIFIED LAWYER: 20 Objection to form. 21 THE WITNESS: I would argue 22 that they were not reasonable. 23 BY MR. BOGLE: 24 Q. Is that an opinion you still</p>

<p style="text-align: right;">Page 1001</p> <p>1 hold today?</p> <p>2 A. That is an opinion I still</p> <p>3 hold today.</p> <p>4 MR. BOGLE: No further</p> <p>5 questions.</p> <p>6 MR. DAVISON: Go off.</p> <p>7 THE VIDEOGRAPHER: Going off</p> <p>8 the record, 5:54 p.m.</p> <p>9 (Brief recess.)</p> <p>10 THE VIDEOGRAPHER: Back on</p> <p>11 record, 5:58 p.m.</p> <p>12 MR. DAVISON: Dr. Whitelaw,</p> <p>13 thank you for your time today. I</p> <p>14 personally have no further</p> <p>15 questions.</p> <p>16 But again as I mentioned</p> <p>17 earlier, reserve the rights for</p> <p>18 the defendants that did not have</p> <p>19 time and for Mallinckrodt because</p> <p>20 we did not get to cover all -- all</p> <p>21 of your opinions.</p> <p>22 MR. BOGLE: Is anybody else</p> <p>23 asking? Or is that for everybody?</p> <p>24 MR. DAVISON: Everybody,</p>	<p style="text-align: right;">Page 1003</p> <p>1</p> <p>2 CERTIFICATE</p> <p>3</p> <p>4</p> <p>5 I HEREBY CERTIFY that the</p> <p>6 witness was duly sworn by me and that the</p> <p>7 deposition is a true record of the</p> <p>8 testimony given by the witness.</p> <p>9</p> <p>10 It was requested before</p> <p>11 completion of the deposition that the</p> <p>12 witness, DR. SETH B. WHITELAW, have the</p> <p>13 opportunity to read and sign the</p> <p>14 deposition transcript.</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <hr/> <p>13 MICHELLE L. GRAY,</p> <p>14 A Registered Professional</p> <p>15 Reporter, Certified Shorthand</p> <p>16 Reporter, Certified Realtime</p> <p>17 Reporter and Notary Public</p> <p>18 Dated: May 20, 2019</p> <p>19 (The foregoing certification</p> <p>20 of this transcript does not apply to any</p> <p>21 reproduction of the same by any means,</p> <p>22 unless under the direct control and/or</p> <p>23 supervision of the certifying reporter.)</p> <p>24</p>
<p style="text-align: right;">Page 1002</p> <p>1 correct.</p> <p>2 THE VIDEOGRAPHER: This ends</p> <p>3 today's deposition. We're going</p> <p>4 off the record at 5:58 p.m.</p> <p>5 (Excused.)</p> <p>6 (Deposition concluded at</p> <p>7 approximately 5:58 p.m.)</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 1004</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it.</p> <p>10 You are signing same subject</p> <p>11 to the changes you have noted on the</p> <p>12 errata sheet, which will be attached to</p> <p>13 your deposition.</p> <p>14 It is imperative that you</p> <p>15 return the original errata sheet to the</p> <p>16 deposing attorney within thirty (30) days</p> <p>17 of receipt of the deposition transcript</p> <p>18 by you. If you fail to do so, the</p> <p>19 deposition transcript may be deemed to be</p> <p>20 accurate and may be used in court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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1           LAWYER'S NOTES

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2           ACKNOWLEDGMENT OF DEPONENT

3

4           I, \_\_\_\_\_, do

5 hereby certify that I have read the

6 foregoing pages, 524 - 1007, and that the

7 same is a correct transcription of the

8 answers given by me to the questions

9 therein propounded, except for the

10 corrections or changes in form or

11 substance, if any, noted in the attached

12 Errata Sheet.

13

14

15 \_\_\_\_\_

16 DR. SETH B. WHITELAW           DATE

17

18

19 Subscribed and sworn

20 to before me this

21 \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

22 My commission expires: \_\_\_\_\_

23 \_\_\_\_\_

24 Notary Public